

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

	x	
	:	
THE CITY OF HUNTINGTON,	:	Civil Action
	:	
Plaintiff,	:	No. 3:17-cv-01362
	:	
v.	:	
	:	
AMERISOURCEBERGEN DRUG	:	
CORPORATION, et al.,	:	
	:	
Defendants.	:	

	x	
	:	
CABELL COUNTY COMMISSION,	:	Civil Action
	:	
Plaintiff,	:	No. 3:17-cv-01665
	:	
v.	:	
	:	
AMERISOURCEBERGEN DRUG	:	
CORPORATION, et al.,	:	
	:	
Defendants.	:	

BENCH TRIAL - VOLUME 18
BEFORE THE HONORABLE DAVID A. FABER, SENIOR STATUS JUDGE
UNITED STATES DISTRICT COURT
IN CHARLESTON, WEST VIRGINIA

MAY 26, 2021

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1 PROCEEDINGS had before The Honorable David A.
2 Faber, Senior Status Judge, United States District
3 Court, Southern District of West Virginia, in
4 Charleston, West Virginia, on May 26, 2021, at 9:00 a.m.
5 as follows:

6 THE COURT: Good morning. Are we ready to go
7 here?

8 MR. FARRELL: Yes, Your Honor.

9 THE COURT: Mr. Farrell.
10 Mr. Fuller.

11 MR. FULLER: Judge, I'm just going to move in some
12 more documents if that's okay with the Court.

13 THE COURT: Well, we'll see. Go quickly.

14 MR. FULLER: What I've been told is it will be
15 easy.

16 The plaintiffs will move in 14296 which is a 1006
17 summary, and 14 -- excuse me -- 42432 which is another 1006
18 summary.

19 MR. SCHMIDT: Mr. Fuller, I don't know what these
20 are. Do these relate to McKesson?

21 MR. FULLER: No, sir, they're Cardinal.

22 MS. WICHT: No objection, Your Honor.

23 THE CLERK: I need the documents.

24 THE COURT: You need to --

25 MR. FULLER: I'm bringing Allison copies now.

1 May I approach, Judge?

2 THE COURT: All right. They're admitted.

3 MR. FULLER: Thank you, Your Honor.

4 MR. ACKERMAN: Real quick, Your Honor, a little
5 bit of clean-up from yesterday.

6 There were three documents we had wanted to move in
7 with Mr. Ashworth. But given the time, McKesson has agreed
8 that we can do it this morning instead of at 5:15 yesterday.

9 I believe two of them there are no objections to and
10 that is P-12820 and P-12883. I have copies.

11 THE COURT: If there's no objection, those two are
12 admitted.

13 MR. SCHMIDT: No objection.

14 MR. ACKERMAN: All right. And then the third
15 document, which I can circulate, is P-54 which is an email,
16 McKesson email dated April 24th, 2013. I'll circulate
17 copies now.

18 THE COURT: Yes.

19 THE CLERK: Where are the ones that just got
20 admitted?

21 MR. ACKERMAN: Your Honor, the ones that just got
22 admitted are still sitting on the podium. I'll give those
23 to you. This is P-12820. This is P-12883.

24 Your Honor, now that I've gotten my steps in, back to
25 P-54. This is an internal McKesson email concerning the

1 process for approving Threshold Change Requests.

2 It is our position that the description of the
3 document, and especially the top two emails, describe a, a
4 process that is applied nationally consistent with the
5 testimony yesterday. The document is not hearsay because it
6 is a statement of an employee within the scope of their
7 employment pursuant to Rule 801(d)(2)(D).

8 THE COURT: Mr. Stanner.

9 MR. STANNER: Thank you, Your Honor.

10 If you flip to the second page of the document you'll
11 see it concerns a couple pharmacies in Ohio. It's not a
12 policy or a procedure. It's an email between two employees
13 outside of this jurisdiction with no connection to Cabell
14 County talking about how threshold changes would be done.

15 It's our position this isn't a reflection of any
16 national policy or procedure. It's just these two employees
17 in a different state talking about their policies for this
18 pharmacy.

19 THE COURT: Well, I'm going to admit it. I think
20 it goes to the weight rather than the admissibility and I'm
21 going to admit it for what it's worth.

22 MR. ACKERMAN: Thank you, Your Honor.

23 THE COURT: Now, you gave me two more.

24 MR. ACKERMAN: Those are the two that there were
25 no objections to. Those are already admitted.

1 THE COURT: Oh, all right. Okay.

2 You can call your next witness.

3 MR. FARRELL: Thank you, Judge. Plaintiffs call
4 expert witness James Rafalski.

5 THE CLERK: Could you state your name for the
6 record, please?

7 THE WITNESS: James Rafalski, R-a-f-a-l-s-k-i.

8 THE CLERK: Would you raise your right hand.

9 **JAMES RAFALSKI, PLAINTIFFS' WITNESS, SWORN**

10 THE CLERK: You may have a seat right there,
11 please.

12 THE WITNESS: Thank you.

13 Good morning, Your Honor.

14 THE COURT: Mr. Rafalski.

15 DIRECT EXAMINATION

16 BY MR. FARRELL:

17 **Q.** Good morning. Would you please state your name for
18 the record?

19 **A.** James Rafalski.

20 **Q.** Mr. Rafalski, what I'd like to do initially is have you
21 introduce yourself to the Court and explain a little bit
22 about your professional background.

23 **A.** Good morning, Your Honor. I'm James Rafalski again.

24 I'd like to start to tell you from my first law
25 enforcement employment.

1 In 1976 I joined the Wayne County Sheriff's Department
2 which is located in Detroit, Michigan. I worked in the
3 Sheriff's Department for five years.

4 In 1981 there was an economic downturn in Detroit -- or
5 in Michigan and they started lay-offs. So I left the Wayne
6 County Sheriff's Department and moved to the Romulus Police
7 Department for the City of Romulus. That's also located in
8 Michigan. It's about 20 miles outside of Detroit.

9 The unique thing about Romulus is the Detroit
10 Metropolitan Airport is right in the center of the city, so
11 they surround it.

12 I started as a patrol officer. I worked my way up
13 through the ranks. In '84 I became a uniform sergeant. '86
14 I became a detective sergeant. '87 I got a unique
15 opportunity. The chief approached me and asked me to start
16 a Special Investigations Unit.

17 So I hand-picked three employees and started a special
18 unit within the police department, complex crime
19 investigations. The start of that unit also coincided with
20 the crack cocaine issues that began in America, especially
21 in the Detroit area. So a majority of the work was working
22 in narcotic cases.

23 It was during the three and a half years that I was
24 head of the Special Investigations Unit we started to have a
25 lot of contact with the DEA. We worked cases that got to a

1 level that didn't exceed our ability, but it exceeded our
2 manpower and our funding.

3 So we would work joint cases with the DEA which led to
4 an invitation from the DEA for me to move from the DEA --
5 from Romulus to the DEA as a Task Force Officer.

6 I worked with the DEA for five years as a Task Force
7 Officer doing illicit drug cases, cocaine, heroin, marijuana
8 cases.

9 Around '95 is when I came back to the department. I
10 took a promotion to uniform lieutenant. So after a long
11 time not wearing a uniform, I came back and worked midnight
12 shift in uniform. That was a tough transition.

13 I went to a community policing unit for a couple years.
14 And then at the end of my career probably around 2000 I was
15 promoted to Executive Lieutenant. It would be similar to
16 actually a deputy chief position. I ran the entire uniform
17 division.

18 In 2002 I got an unexpected offer for a buy-out, a
19 retirement buy-out. The department made a decision to offer
20 retirement to all of the command officers.

21 So it was one of those offers -- I hadn't planned on
22 retiring. I kind of had my eye on the police chief job
23 there. And -- but it was too good to pass up, so I retired.

24 I was 48 years old and I knew that I wasn't not going
25 to work anymore. Upon leaving, I put applications in at the

1 DEA and the Traffic Safety Administration.

2 Q. Mr. Rafalski, I'm going to stop you right there before
3 we move on.

4 MR. FARRELL: Judge, I have attempted to outline
5 and provide a roadmap to today's testimony. And I have
6 demonstrative slides that I think you'll find that the
7 witness will testify is helpful in his testimony.

8 I've provided copies to counsel. And what I would like
9 to do is I'd like to present you with a copy and publish the
10 front page.

11 MR. SCHMIDT: Your Honor, two comments on these
12 slides.

13 The first is there is at least one slide in here that
14 we don't believe they have a proper foundation for because
15 it relates to data from Dr. McCann that was never presented
16 to the Court where that portion of Dr. McCann's testimony is
17 now over.

18 The second point, more broadly, that we can deal with
19 as it comes up is we had this happen with Dr. Waller, the
20 Court will remember, the first expert witness where slides
21 were used to lead him through his testimony. And some of
22 these slides look like they would have the same effect.

23 We can object to them as we go, but it shouldn't be the
24 case that the witness is testifying by lawyers reading off
25 of slides or something like that.

1 MS. MAINIGI: Your Honor, --

2 THE COURT: We'll have to see where you go, Mr.
3 Farrell.

4 Yes, Ms. Mainigi.

5 MS. MAINIGI: Your Honor, I join in Mr. Schmidt's
6 comments. I think that there are a couple of slides in here
7 that we would also have objections to perhaps different than
8 McKesson, but I'm happy to take it as well.

9 THE COURT: Okay. Yes, Mr. Nicholas.

10 MR. NICHOLAS: Just for the record, we don't
11 object to the concept of this. I think we just have to take
12 it slide by slide.

13 THE COURT: Well, I think we do too.

14 Go ahead, Mr. Farrell.

15 MR. FARRELL: Thank you.

16 Judge, as you'll see, there's eight steps to what we
17 believe to be the testimony today: The introduction, which
18 we've just gotten through, and then we intend go through his
19 qualifications, his methodology, the purpose of why he's
20 here, the guidance materials he relied upon, the reliance
21 materials that are in the record, which would be followed by
22 his findings and, if permitted, his final opinions.

23 BY MR. FARRELL:

24 Q. So, Mr. Rafalski, what I'd like to do is let's jump
25 into the section of qualifications where you joined the

1 DEA.

2 Can you walk the Judge through what your role initially
3 with the DEA was and what your function and job
4 responsibilities were?

5 **A.** Are you talking the first time I was there or are you
6 talking my employment there when I began my employment as a
7 diversion investigator?

8 **Q.** I think we can skip over the Task Force participation.
9 Let's talk about when you were formally hired by the DEA.

10 **A.** In September of 2004 I received an employment offer
11 from the DEA, Your Honor, and I accepted it. And I went for
12 12 weeks to a -- we call it custodial academy, an in-house
13 academy in Quantico, Virginia.

14 Upon the completion of the 12 weeks -- it was pretty
15 rigorous academic training, actually, with some practical
16 examinations. I graduated and returned to the Detroit,
17 Michigan, divisional office in December of 2004.

18 **Q.** So what was your first assignment? What was your first
19 posting with the DEA?

20 **A.** When I got there, the job was kind of three specific
21 areas. One is an administrative area. Those are the duties
22 that -- and assignments that just come at you as part of
23 your employment. Registration renewals.

24 **Q.** Mr. Rafalski, I'm sorry. Let me back up. Maybe I
25 missed it. What was your actual title and job designation?

1 **A.** Sure. Diversion investigator. And when -- I think the
2 Court's hearing people testify, and you may know this, Your
3 Honor. As a diversion investigator, I'm different than an
4 agent. I can do essentially some of the same things an
5 agent can do, but I'm not a law enforcement officer.

6 So I did not carry a gun. I did not have arrest
7 powers, could not serve search warrants, could not handle
8 confidential informants. So there were some restrictions on
9 my job, but I could conduct investigations.

10 **Q.** Okay. Now, for a diversion investigation, in general
11 what was the -- what is it that you were looking to
12 regulate? What, what portions of America in the
13 transactions were you studying for purposes of the DEA?

14 **A.** The job is focused, Your Honor, on registrants, those
15 people that hold DEA registrations and have the ability to
16 handle controlled substances.

17 **Q.** Okay. And will you walk the through judge -- the Judge
18 through briefly what different registrants there are in the
19 closed system?

20 **A.** At the top of the system, the closed system would
21 probably be the importers. Those would be the registrants
22 that could bring the raw narcotic material into the country.

23 Next would be the manufacturers. And there's different
24 levels of manufacturers. There's raw product manufacturers
25 and dosage manufacturers that eventually turn the narcotics

1 into pills and liquids and gels.

2 Those would flow through and down to the distributors.
3 And from the distributors, they would flow down to those
4 registrants that could purchase and handle the controlled
5 substances; pharmacies, practitioners. And when I say a
6 practitioner, it would be a doctor. But it could be
7 different kinds of doctors; veterinarians, dentists, medical
8 doctors. There would also be researchers.

9 And I'm sure I've forgot one or two, but that would be
10 generally the, the circle of the people that would handle
11 the drugs in the closed system.

12 **Q.** Which of those registrant classifications did, did you
13 participate in investigations with while you were at the
14 DEA?

15 **A.** All, all of those classifications, or those types of
16 descriptions. Maybe not researches -- I would investigate
17 them, but not for illicit purposes. But I would have
18 contact and would do administrative investigations for all
19 of those types of businesses.

20 **Q.** Were you assigned to a particular geographic area?

21 **A.** Yes, sir.

22 **Q.** Which was your geography?

23 **A.** In the Detroit office I would cover the lower peninsula
24 of Michigan, the upper peninsula of Michigan, and I would
25 cover six counties in Ohio, six northern east counties in

1 Ohio.

2 **Q.** Approximately how many investigations did you
3 participate in or did your, your Task Force -- your group in
4 Detroit participate in?

5 **A.** Oh, over the 13 years I would say approximately 40 to
6 50 investigations. Those would be major investigations.
7 There would be smaller investigations, maybe a doctor that
8 that had some licensing issues or had some issues at the
9 state level that I would investigate as part of our
10 administrative assignment. I wouldn't count those. These
11 are just more of higher level investigations.

12 **Q.** Would you walk the Judge through a couple of examples
13 of notable investigations that you participated in?

14 **A.** Certainly.

15 Your Honor, when I arrived in Detroit, immediately I
16 was assigned to assist in an investigation of a gentleman
17 named Dr. Leo Ognen. He was a Yugoslavian lieutenant and a
18 military doctor that came to America. He was in Toledo,
19 Ohio.

20 And I guess if you were hearing the term "pill mill,"
21 his office was the definition of a pill mill; patients
22 sleeping in the office, crowds in the parking lot, fights.
23 Sometimes the doctor would be out in the parking lot smoking
24 cigarettes with his patients.

25 He was writing Oxycontin 80 milligrams. He was writing

1 sub drugs, other oxycodone combinations and Xanax. A large
2 population of, of patients grew rather quickly in the Toledo
3 area and there was a big change in Toledo as a result of
4 Dr. Ognen's actions.

5 We investigated that case, took a lot of interviews and
6 record reviews. And prior to trial, Dr. Ognen pled guilty.

7 **Q.** Okay. What other notable investigations?

8 **A.** My next case was another doctor case, but it was a more
9 sophisticated distribution case. As time went on, pill mill
10 doctors still were present, but this doctor was actually a
11 source of supply of some narcotic organizations.

12 So there were four organized groups with leaders. And
13 this physician would meet them in the office or sometimes
14 outside the office in parking lots and he would sell them
15 prescriptions for cash.

16 So he was feeding prescriptions to these four groups.
17 And these four groups were primarily going to the same
18 pharmacy and cashing these prescriptions and distributing.
19 Again, it was an Oxycontin 80-milligram case, and the same
20 subset. The Percocet 10-milligram combination oxycodone and
21 Xanax were the two most common drugs.

22 **Q.** Have you participated in the investigation of any
23 wholesale distributors?

24 **A.** Yes, sir, I have.

25 **Q.** Would you please tell the Judge a couple of the notable

1 examples?

2 **A.** The first case, Your Honor, would be the Harvard Drug
3 Group. That case originated -- the management in Detroit,
4 because of the, the pill mill operations or pain clinic --
5 I'm sorry -- operations in Florida, tasked some people in
6 Detroit to, to check all of the distributors to make sure
7 none of the Detroit area distributors were sending opioids
8 or, more specifically, oxycodone down to Florida.

9 Well, a little advance investigation determined that
10 Harvard was sending a large amount of oxycodone 30-milligram
11 tablets to doctors in South Florida.

12 As a result of finding that information, I did some
13 background information which led to issuing an
14 administrative inspection warrant.

15 An administrative inspection warrant, Your Honor, is
16 similar to a search warrant, but it's restricted into what
17 you can see and what you can look at. It's more of an
18 ability to go in and obtain the required records and conduct
19 the investigation.

20 I executed the administrative inspection warrant. I
21 made contact with the management and compliance at Harvard.
22 I'd have to say that was a good experience for me. They
23 were very helpful and very open and honest moving forward.

24 I took that information and came back and conducted
25 some interviews which led to an Immediate Suspension Order

1 and Order to Show Cause.

2 And what that, what that entails, Your Honor, is I get
3 an order from chief counsel in DEA and I walk in the door
4 and I essentially stop them from handling drugs.

5 In the first case I dealt with, I didn't realize the
6 totality of the things I did. One of the things is I had to
7 count all of the pills in the facility before I left. I
8 wasn't alone. I took the whole group with me. But there's
9 a lot of pills and liquids and things stored in a, in a
10 distributor.

11 So we spent the whole day and into the evening counting
12 all the pills. And then upon leaving, we put some stickers
13 on the doors and, and they weren't able to handle controlled
14 substances while under the Immediate Suspension Order.

15 THE COURT: Does it have any connection to Harvard
16 University?

17 THE WITNESS: No, it does not, but they had a logo
18 that looked a little similar to Harvard.

19 BY MR. FARRELL:

20 **Q.** So what was the year that the investigation began?

21 **A.** 2010, Your Honor.

22 **Q.** When did it end?

23 **A.** 2011. During the course of the investigation they had
24 some meetings with the United States Attorney's Office and
25 the chief counsel for DEA. And they came to an agreement to

1 settle the case and they entered into a Memorandum of
2 Agreement.

3 **Q.** Aside from the Harvard wholesale distributor, are there
4 any other notable investigations?

5 **A.** While I was concluding Harvard, I was assigned by my
6 supervisor to begin an investigation on Masters
7 Pharmaceutical which was located just outside of Cincinnati,
8 Ohio, same basic methodology or investigation.

9 **Q.** Mr. Rafalski, I'm going to interrupt you real quick
10 just to make one emphasized point. Who was the lead
11 investigator in the Masters Pharmaceutical case which has
12 been referenced throughout this trial?

13 **A.** That would be me, sir.

14 **Q.** What year was Masters investigation began?

15 **A.** I started looking at it in 2010. Probably the official
16 case didn't start until early 2011.

17 **Q.** And do you recall when that investigation -- or when
18 that case ended?

19 **A.** It ended in -- I believe on June 30th of 2017.

20 **Q.** Will you explain to the Judge now a little bit of the
21 history of your investigation into Masters Pharmaceutical?

22 **A.** I did some background before going on-site. They had
23 been under a Memorandum of Agreement, Your Honor, for their
24 handling of controlled substances and distribution during
25 the internet, illicit internet activity.

1 The DEA had done a case on them and they had come to a
2 resolution. They were under an MOU. I did a lot of
3 research on the Memorandum of Agreement. I looked at their
4 distribution patterns.

5 When I looked at that case and I saw the amount of
6 oxycodone 30 going to some of the pharmacies, it had a
7 strong indication that it wasn't going to be a close call.

8 But, you know, moving forward, I gathered all the
9 information before I walked into the, to the business. I
10 came in unannounced, sat down with the management the first
11 day. We had a discussion. I conducted some interviews,
12 reviewed some customer files, obtained some transaction data
13 from them, and started my investigation.

14 **Q.** What did your investigation reveal?

15 **A.** Well, I had a couple more steps. I served an
16 administrative subpoena and I took a couple dozen customer
17 files. We would call them customer files. Some people
18 would refer to them as due diligence files. Those would be
19 the files on all the, the activity they took to make sure
20 that they were maintaining effective controls for the
21 prevention of diversion.

22 **Q.** Let me stop you there for a second. When you go and
23 obtain a customer file, what is your expectation or what has
24 been your experience as to what that file looks like and
25 what's in it?

1 **A.** My, my experience has been that they're sometimes
2 pretty voluminous files. They're -- depending on the time
3 frame back then, they were probably a lot of paper. So they
4 would come out with a paper file, and sometimes they would
5 also have electronic files that they could provide you on a
6 CD. And it would be -- most of them would have a chronology
7 of what they had done with each of their customers. Each of
8 the files was specific to a customer.

9 **Q.** Okay. And tell the Judge what the, or the findings
10 that you made on the investigation.

11 **A.** Well, after looking at all of the information and, and
12 reviewing all of the customer files, to me it was clear that
13 they had a failure to maintain effective controls to prevent
14 diversion.

15 In this case they had a functioning Suspicious Order
16 Monitoring System. But within their company, they had some
17 procedures they should follow when they identified a
18 suspicious order. And they were avoiding those procedures
19 which allowed them to continue to ship large volumes of the
20 oxycodone 30 and 15 pills down to Florida.

21 **Q.** And did you find and make the recommendation that the
22 pills -- the suspicious orders that Masters Pharmaceutical
23 failed to identify and detect were likely to be diverted?

24 **A.** I did.

25 **Q.** And did you make a finding that the continued

1 registration of this facility was -- posed imminent harm to
2 the public?

3 **A.** Yes, I did, Your Honor.

4 **Q.** So let's walk through the procedural history.

5 MR. FARRELL: The case is a reported case, Judge.

6 BY MR. FARRELL:

7 **Q.** I just want to walk through very briefly what your
8 experience was with the procedural history of the
9 administrative action.

10 **A.** You mean post order to show cause?

11 **Q.** Yes, please.

12 **A.** Okay.

13 MS. MAINIGI: Your Honor, I'm going to object on
14 relevance. We've gotten some background on this. I'm not
15 sure what the purpose is of going through the procedural
16 history of some other case all together that he investigated
17 as a DEA investigator.

18 THE COURT: It has to do with his qualifications
19 as an expert, doesn't it? Are you offering him as an
20 expert?

21 MR. FARRELL: Yes. If you like, I can go straight
22 to the proffer and see if they object.

23 THE COURT: Well, that's up to you. You're the
24 lawyer, Mr. Farrell.

25 MR. FARRELL: We'll continue for a few minutes

1 then.

2 THE COURT: I'll overrule the objection at this
3 point.

4 BY MR. FARRELL:

5 Q. Okay. Please continue.

6 A. Once I assembled all of the, the data and files and
7 information I had and I reviewed them all, I, I take that
8 information and I complete a report, the report of my
9 findings. And I submit that report up through my
10 management. And then it goes to attorneys in headquarters,
11 chief counsel attorneys, and they review my work and, and
12 either confirm or not confirm my findings.

13 In that particular case, looking at all of the conduct
14 by the company, it was, it was a systematic long-term issue.
15 As I said earlier, this was not a close call of the conduct
16 of the company.

17 So I would fully document it and document, you know,
18 the information I found. I would look at the customer files
19 and analyze those. I would look at the transactional data.
20 I would conduct interviews and capture all that information
21 and, upon reviewing it, complete a report, detailed report.

22 Q. All right. So have you outlined in general the
23 framework of your methodology when performing investigations
24 while you were at the DEA?

25 A. Yes, Your Honor.

1 **Q.** So did you prepare a slide that outlined your
2 methodology?

3 **A.** Yes, I did.

4 **Q.** And would that slide be helpful and assist you in
5 outlining your methodology to the Court?

6 **A.** Yes, it would.

7 MR. FARRELL: Judge, at this time I'd like to
8 publish slide 2 unless there's objection.

9 BY MR. FARRELL:

10 **Q.** All right. Will you please explain to the Judge
11 and walk him through what it is that you prepared and
12 what it represents.

13 **A.** The first one on the list, Your Honor, A is the
14 transactional data. That would be the sales for Masters --
15 or their distribution of controlled substances.

16 Second one is the policy and procedures. I would
17 obtain and gain the policies and procedures of the company.
18 I would also, upon getting them, try to have an interview
19 with the, the employees to try to determine if they actually
20 had knowledge of their policies and procedures and following
21 them.

22 I would also discuss with the employees and their SOMS,
23 which stands for Suspicious Order Monitoring system, I'd get
24 a verbal description, and hopefully in the procedures I'd
25 get a written description.

1 The purpose of discussing it was to make sure they
2 understood their system and that they were, they were using
3 it.

4 I would do interviews. Some of those interviews would
5 be where companies were open, they'd give me access to
6 employees, not often in the Masters case. The first day I
7 did some, some interviews on-site, but it was not as
8 cooperative as with the Harvard Drug Group.

9 I would obtain customer files. I would look at some
10 on-site. In the case of Masters, I would -- I had an
11 administrative subpoena with me to obtain some of the files
12 that I had already targeted prior to arriving.

13 I would also look at internal documents, another
14 essential part. So those would be emails, communications,
15 any kind of documentation that had to deal with the handling
16 of controlled substances and the distribution.

17 And then, finally, I would ask for their suspicious
18 orders they had reported to the DEA, and also if they were
19 maintaining a list of all the orders they stopped prior to
20 shipping because of the suspicious order system.

21 **Q.** After obtaining the information, what factual findings
22 would you make?

23 **A.** I would look through all of that data and I would try
24 to make a determination -- I would make a determination
25 whether the registrant had effective controls to prevent

1 diversion of controlled substances.

2 And, secondly, I would also look to see if they had
3 designed and operated a suspicious order system that was
4 functioning and was able to actually accomplish the mission
5 of blocking a suspicious order.

6 **Q.** And would you be the one to make the final
7 determination as to the action taken?

8 **A.** I would not.

9 **Q.** Who would make that decision?

10 **A.** Well, in the case of when I was employed, I would
11 complete a report and I would push it through the channels
12 of the DEA. And it would ultimately flow to the chief
13 counsel in Washington, D.C. and they'd make that decision.

14 I think today I'm here and I'm presenting my facts and
15 findings to you, Judge, instead of my prior employment with
16 the DEA.

17 **Q.** That leads me to a nice transition point. What is it
18 that you believe is your purpose and role here today? What
19 have we asked you to come and do?

20 **A.** I think you've asked me essentially, Your Honor, to do
21 the same thing I did when I was working with the DEA. And
22 that's to examine those same types of records and documents
23 that are up on the screen in regards to the three
24 defendants, AmerisourceBergen, Cardinal, and McKesson, and
25 come to the same factual findings on whether these three

1 companies maintained effective controls to prevent the
2 diversion of controlled substances, which is the most
3 important because that's like the foundation of all security
4 regulations, and whether the registrants had designed and
5 operated a Suspicious Order Monitoring System to identify,
6 block, and report the distribution of controlled substances
7 that could be diverted.

8 MR. FARRELL: Judge, at this time we ask that Mr.
9 Rafalski be qualified as an expert in the field of diversion
10 control investigations, Suspicious Order Monitoring Systems,
11 and maintenance of effective control to prevent diversion of
12 controlled substances into the illicit market, and ask that
13 he be permitted to present his investigative findings and
14 conclusions to the Court in this matter.

15 THE COURT: Any objection?

16 MR. SCHMIDT: Yes, Your Honor.

17 We filed a motion before trial, a *Daubert* motion
18 regarding Mr. Rafalski's methodology. I think your Court's
19 ruling was that we would maintain those arguments subject to
20 a wide berth of examination on cross-examination.

21 So we will maintain that argument and then, as
22 appropriate, renew that motion at the end of trial.

23 Also, I did not hear this. Is he being offered on
24 causation, Mr. Farrell?

25 THE COURT: Ms. Mainigi.

1 MS. MAINIGI: Oh, I think there's a question
2 pending, sir.

3 MR. SCHMIDT: Yeah. We do have a qualifications
4 challenge if he's being offered on causation. I didn't
5 understand that to be one of the topics which is why I asked
6 that courtesy question, counsel.

7 THE COURT: Let me hear from counsel, Mr. Nicholas
8 and then Ms. Mainigi.

9 MR. NICHOLAS: We reserve our objection on the
10 same grounds that Mr. Schmidt has articulated, and I would
11 have the same question. I, I don't believe this witness is
12 being offered as an expert on causation. If that were the
13 case, we would object on that ground as well, but I don't
14 think that's what we heard.

15 MS. MAINIGI: Your Honor, on this last point, I do
16 not believe that the witness is being offered as an expert
17 on causation. If he were, we would object. But I've not
18 seen anything or heard anything that would be suggestive of
19 that.

20 In addition to the -- it does seem clear to us, as Mr.
21 Schmidt said, that Your Honor would like to make decisions
22 about the admissibility of certain testimony as you are
23 perhaps proceeding, or after you've had a chance to hear it
24 all. So we're certainly mindful of that.

25 But I certainly think that some of what has been

1 articulated for Mr. Rafalski as potential opinions goes also
2 to the heart of what Your Honor excluded in the Geldhof
3 motion.

4 So I think as those opinions regarding what the law
5 requires or whether certain conduct violated the law are,
6 are certainly opinions that in advance I'll note that we
7 would have objection to.

8 THE COURT: Are you offering him as an expert on
9 causation?

10 MR. FARRELL: To the extent that he has opinions
11 about whether or not the failure to maintain effective
12 controls more likely than not results in diversion, the
13 answer is "yes." For purposes of specific causation, no.

14 MR. SCHMIDT: Well, I'm not sure I understand that
15 distinction, but he's not qualified to give a causation
16 opinion. He's not purported to do so in his report and he's
17 not used a valid methodology for doing so.

18 THE COURT: Mr. Nicholas.

19 MR. NICHOLAS: I agree.

20 THE COURT: Well, I think the thing to do is hear
21 his testimony and reserve ruling on this.

22 And subject to that, I'll let you go ahead, Mr.
23 Farrell.

24 MR. FARRELL: Thank you, Your Honor.

25 BY MR. FARRELL:

1 Q. Mr. Rafalski, --

2 MR. FARRELL: So do I need to repeat my request
3 for his qualifications or do we accept it or just proceed?

4 THE COURT: I don't understand what you're driving
5 at here.

6 MR. FARRELL: We've asked for the Court to
7 recognize him as a qualified expert in certain fields and
8 I'm not sure that we got to the answer.

9 THE COURT: Well, my answer was that that was
10 subject to objection, if I understood it correctly. And I
11 thought I would go ahead and hear the testimony and reserve
12 ruling on that because if, if I agree with the defendants,
13 then, then it all goes out the window. But I think I'll
14 hear it and give you a chance to put it in before I make
15 that decision. So that's where we'll go.

16 MR. FARRELL: Thank you, Judge.

17 THE COURT: Okay.

18 BY MR. FARRELL:

19 Q. Mr. Rafalski, in the course of your investigation
20 in this case, are there materials that you relied upon
21 for guidance?

22 A. Yes, sir, there are.

23 Q. And have you prepared a slide of the guidance materials
24 that you relied upon?

25 A. Yes, I have.

1 **Q.** Would that slide be helpful for you and assist you in
2 your testimony today?

3 **A.** Yes, it would, Your Honor.

4 MR. FARRELL: Judge, at this time I'd like to have
5 published the guidance material slide.

6 For orientation purposes, Your Honor, and to counsel,
7 the documents that are referenced in black have been
8 admitted. The documents that are referenced in red are
9 pending and have not yet been admitted.

10 And the precedent that is in the -- for items 6, 8 and
11 9 are in red and they likewise are not admitted into the
12 record.

13 BY MR. FARRELL:

14 **Q.** Mr. Rafalski, without belaboring the point, will
15 you -- are these the materials that you relied upon as
16 guidance when performing your investigation?

17 **A.** Yes, sir, Your Honor, they were.

18 MR. FARRELL: Judge, I think as a matter of
19 course, I'd like to have this Page 3, which would be
20 Demo223_0003, identified and tendered to the Court.

21 MR. SCHMIDT: I don't object to it being a
22 demonstrative for the court record. If you're moving it
23 into evidence, we do object to that.

24 MR. FARRELL: I just would like it available to
25 the Court if the Court finds it helpful.

1 THE COURT: Well, if that's a demonstrative,
2 that's proper, isn't it, Mr. Nicholas?

3 MR. NICHOLAS: Yes. I just wanted to make sure I
4 understand that this is meant to illustrate guidance for the
5 witness and not guidance for the distributors.

6 MR. FARRELL: Yes, Your Honor.

7 MS. MAINIGI: That's exactly the clarification I
8 wanted to make, Your Honor, because certainly there are a
9 number of legal cases in this document which goes to my
10 earlier point.

11 THE COURT: I understand.

12 And you do too, Mr. Farrell.

13 MR. FARRELL: Yes, Your Honor.

14 THE COURT: Go ahead, please.

15 BY MR. FARRELL:

16 Q. Have you also prepared a list of the discovery
17 responses and the facts, the reliance materials during
18 your investigation?

19 A. Yes, I have.

20 Q. And have you compiled that list and disclosed it?

21 A. Yes, I have.

22 Q. So, very briefly, have you prepared an overview of the
23 types of documents that you relied upon?

24 A. I have.

25 Q. And have you placed those on a slide for the Court?

1 **A.** Yes, I have, Your Honor.

2 **Q.** And would reviewing that slide be helpful and assist
3 you in your testimony?

4 **A.** Yes, it would.

5 MR. FARRELL: I'd like to show it to the Court.
6 The next slide is already up.

7 BY MR. FARRELL:

8 **Q.** So walking through 1 through 8 on Demo223_4, is
9 this the similar methodology that you used when you were
10 exercising and performing your responsibilities for the
11 DEA?

12 **A.** Yes. One of the -- not exceptions, but number 5, the
13 depositions, that would be a substitute for interviews. I
14 did not have an opportunity to actually interview employees
15 of the defendants. But everything else would be very
16 similar to what I used as an investigator with the DEA.

17 THE COURT: I'm not clear, Mr. Farrell, on what
18 the difference is between the guidance materials and the
19 reliance materials.

20 MR. FARRELL: So would you like me to answer or
21 the witness?

22 THE COURT: Well, can you answer it, Mr. Rafalski?

23 THE WITNESS: Yeah. The previous list, those
24 guidance materials, it kind of gives a roadmap to me of some
25 of the activity historically that came down back from 1984,

1 gave me an idea of the history of what the guidance was to
2 the defendants.

3 Some important rulings were there. *Southwood* was a
4 very important ruling. That's an administrative action that
5 there was a hearing and it was published in the Code of
6 Federal Regulations.

7 The Rannazzisi letters, those were important to me.
8 What was the guidance --

9 BY MR. FARRELL:

10 **Q.** Excuse me. I think what might be a better
11 course -- can we back up one slide?

12 Let's just take the guidance materials and very briefly
13 walk through them, 1 through 12.

14 Will you tell the Court what you relied upon from the
15 NWDA SOMS from 1984 which is conditionally marked as P-2094?

16 **A.** I believe that was -- NWDA is a trade association that
17 manufactures and distributors belong to. That was a SOMS, a
18 Suspicious Order Monitoring System. I think that was the,
19 the first time that there was a system that was designed and
20 it was by the NWDA.

21 Also included there, there was some participation with
22 the DEA. There was a Mr. Gitchell (phonetic) that was
23 involved. And I don't know if he provided guidance, but he
24 definitely was collaborating with the NWDA. And he's had
25 some letter communications that had some interesting

1 guidance.

2 The next is the DEA investigators manual. That was
3 actually obtained by Cardinal Health through a FOIA request.
4 The manual was 1996. I believe they, they actually obtained
5 that some years later.

6 The next, number three, is the 1998 Reno report. That
7 was a, a conference -- or actually a committee that met for
8 the Attorney General, and it was in regards to the
9 Methamphetamine Act.

10 They had some recommendations. I think some of the --
11 I think the defendants -- some of the defendants relied on
12 some of the guidance in the Reno report that was targeting
13 List I chemicals and how to handle those because they were
14 used in the illicit manufacture of methamphetamine.

15 The next is the DEA Chemical Handlers Manual. That's
16 tied in with the Reno report. And I think the Reno report
17 relied on -- some of the information that the DEA published
18 in the Chemical Handlers Manual. I believe it was specific
19 to List I chemicals and not to controlled substances.

20 And List I chemicals, Your Honor, are those chemicals
21 that can be used to directly manufacture illicit controlled
22 substances, the top one being in America for some time was
23 methamphetamine.

24 The next is a DEA Linden Barber memo. That was
25 important because Linden Barber was the head of chief

1 counsel's office, attorney for the DEA. And that memo
2 directly supported or confirmed Mr. Rannazzisi's letters
3 that went out sometime a little later from Mr. Linden
4 Barber's memo.

5 The next is the *Southwood Pharmacy, Inc.* That was an
6 interesting case of distribution by a distributor, Southwood
7 Pharmacy, to rogue internet pharmacies.

8 Essentially, there were huge amounts of hydrocodone
9 products distributed. The DEA took administrative action
10 and it led to an Order to Show Cause hearing which was
11 published in the Federal Register.

12 That's important to me because that was something that
13 was aware to the industry when it gets published.

14 THE COURT: Mr. Schmidt.

15 MR. SCHMIDT: Your Honor, I think we're just --
16 we're doing what Your Honor flagged in the pre-trial rulings
17 as impermissible, just reading things into the record and,
18 in this case, actually construing court decisions, making
19 comments that some defendants relied on some things, which
20 we don't agree with and there's no identification of who it
21 is. It should be limited to questions and answers where we
22 can object properly as opposed to a narrative like the Court
23 addressed pre-trial.

24 THE COURT: Well, I think I did.

25 If I understand your objection, this is a format where

1 you can't specifically object to parts of it.

2 MR. SCHMIDT: Yes, Your Honor.

3 THE COURT: Well, I'm going to let him go through
4 it and maybe you can speed it up and summarize it a little
5 better.

6 THE WITNESS: I can shorten it for you, Your
7 Honor.

8 THE COURT: And --

9 MR. SCHMIDT: No, I was just -- I didn't want to
10 sit down before Your Honor was done.

11 THE COURT: Well, let's do it that way and I'll,
12 I'll overrule your objection for now, Mr. Schmidt.

13 Go ahead, Mr. Farrell.

14 MR. SCHMIDT: Thank you, Your Honor.

15 THE WITNESS: If I understand --

16 THE COURT: Go ahead, please.

17 BY MR. FARRELL:

18 **Q.** So I think we've gotten down to the *Southwood*
19 *Pharmacy* case. Is the *Southwood Pharmacy* case, this is
20 in the Federal Register and it's a DEA action against a
21 distributor; correct?

22 **A.** Yes, sir.

23 **Q.** And then the same goes for the *Cardinal Health* vs.
24 *Holder* and *Masters Pharmaceutical*. Those are reported cases
25 of actions taken by the DEA against wholesale distributors?

1 **A.** Yes, sir.

2 **Q.** Now, looking up here at 1 and 7, NWDA Suspicious Order
3 Monitoring System and HDMA Industry Compliance Guidelines,
4 what's the difference between the NWDA and the HDMA, if you
5 know?

6 **A.** It's the same organization, just a name change.

7 **Q.** And, so, in 1984 and again in 2008 you relied upon as
8 guidance industry guidelines published by the trade group;
9 is that right?

10 **A.** Yes, sir.

11 **Q.** And then you also reviewed the Rannazzisi letters from
12 '06 and '07?

13 **A.** Yes, sir.

14 **Q.** And you reviewed the DEA administrative actions?

15 **A.** Yes, sir.

16 **Q.** And you also reviewed the CSA and CFR. Does this
17 generally describe the materials that you relied upon in
18 guidance when you initiated the investigation on our behalf
19 in this case?

20 **A.** Yes, I did, Your Honor.

21 **Q.** Now go to the next slide, please.

22 Now, the types of documents that you reviewed in this
23 case, have you made a list of those materials that you
24 relied upon?

25 **A.** Yes, I have.

1 MR. FARRELL: Judge, without belaboring the
2 point -- I think I've already circulated this to
3 everybody -- this is again for demonstrative purposes. This
4 is a copy from his expert witness report that we're simply
5 tendering that is a compilation of his reliance materials.

6 BY MR. FARRELL:

7 **Q.** Will you advise the Court in general the types of
8 documents that you reviewed when performing this
9 investigation?

10 **A.** As listed on my reliance materials, Your Honor,
11 discovery responses specific to the Cabell County and
12 Huntington City area; transaction data summaries; -- that
13 would be the distribution records of controlled
14 substances -- the policies and procedures for each of the
15 three companies; the SOMS systems, the Suspicious Order
16 Monitoring Systems for the three companies during the
17 timeline of the investigation; depositions of the employees
18 of the defendants or witnesses for the defendants; the
19 customer files for each of the three defendants, or what's
20 sometimes referred to as the due diligence files; internal
21 documents; -- those would be memos, communications,
22 emails -- and a list or compilation of the suspicious orders
23 both blocked and reported to the DEA.

24 **Q.** Can we flip back to the original first page, please?

25 MR. FARRELL: Judge, just for purposes of

1 orientation, we've gone through 1, 2, 3, 4, 5 and 6, and we
2 have two items left, 7 and 8, his findings and final
3 opinions.

4 THE COURT: We're going to have to take an early
5 break here to change court reporters again.

6 MR. FARRELL: I was stalling hoping that was --

7 THE COURT: This is an appropriate time to do
8 that. Let's come back at 10:00.

9 You can step down during the break.

10 THE WITNESS: Thank you, Your Honor.

11 (Recess taken at 9:49 a.m.)

12 THE COURT: Just so my ruling on this testimony
13 will be clear and, hopefully, I won't make it less clear by
14 saying this, but as I indicated before, I'm going to
15 conditionally admit this testimony and hear it. I realize a
16 bench trial does not eliminate the need to decide whether
17 proper expert opinions meet the requirements of 702, which
18 means I'll have to do a *Daubert* analysis at some point. It
19 does allow the Court to defer that determination until after
20 presentation of the witnesses.

21 And I'm going to exercise my discretion to allow the
22 challenged experts to testify and admit their testimony
23 conditionally subject to later determination as to whether
24 it meets the standards to qualify him as an expert and also
25 whether or not his opinions will be an admissible. And so,

1 it is going to be conditionally admitted at this point
2 subject to later reconsideration.

3 MR. FARRELL: I'll take it, Judge.

4 THE COURT: You may resume, Mr. Farrell.

5 BY MR. FARRELL:

6 **Q.** Mr. Rafalski, I think the next section that we're going
7 to get into is your findings and can you bring up Slide 5?
8 The first component of your methodology was to review
9 transactional data. So, I have a couple of preliminary
10 questions for you, sir. Were you provided the transactional
11 data referencing the defendants and their distribution of
12 controlled substances into Huntington, Cabell County, West
13 Virginia?

14 **A.** Yes, I was, Your Honor.

15 **Q.** And were you able to identify the temporal scope of
16 that data?

17 **A.** Yes, I was, Your Honor.

18 **Q.** And did you prepare a slide that depicts your findings
19 regarding the temporal scope of the data which was provided?

20 **A.** Yes, I did.

21 **Q.** And would publishing that slide assist you in your
22 testimony today?

23 **A.** Yes.

24 MR. FARRELL: Judge, we'd ask for Slide 6 to be
25 published.

1 THE COURT: All right.

2 BY MR. FARRELL:

3 Q. Now, in general, this is a timeline from '95 through
4 2020. Will you walk the Court through what you're trying to
5 communicate with this slide?

6 A. Your Honor, looking at the slide, looking from the top
7 down, the top orange bar would indicate that's McKesson and
8 that bar would indicate that the distribution data that I
9 worked with would begin in 2004 through 2018.

10 Dropping down, the AmerisourceBergen Company, that
11 would be the blue bar. That would be transactional data
12 from 2002 through 2018.

13 The third bar, Cardinal Health, that would indicate
14 there's transactional data from 1996 through 2018.

15 And then the green bar is the ARCOS data and that would
16 be the data that was obtained from the Drug Enforcement
17 Administration and that covered a time period of 2006
18 through 2014.

19 MS. MAINIGI: Your Honor, I don't mean to
20 interrupt the flow. I just want to put in an objection
21 simply for the record, an ongoing objection related to the
22 use of Cardinal data. It significantly pre-dates the other
23 data.

24 THE COURT: All right. I'll overrule that
25 objection for now.

1 Go ahead, Mr. Farrell.

2 BY MR. FARRELL:

3 **Q.** So, Mr. Rafalski, we're going to get into some
4 discussion about the number of transactions and the volume
5 of pills and, to Cardinal Health's point, we have a much
6 longer time frame of data from Cardinal Health than we do
7 the other two; is that right?

8 **A.** That's correct.

9 **Q.** And did you take that into account when you were doing
10 your investigation?

11 **A.** Yes, I did.

12 MS. MAINIGI: Objection to the continuing use of
13 the word investigation, Your Honor. Mr. Rafalski is a paid
14 expert. He's not an investigator.

15 THE COURT: Well, don't call him an investigator
16 unless he is, Mr. Farrell.

17 MR. FARRELL: Yes, Your Honor.

18 BY MR. FARRELL:

19 **Q.** Were you able to identify the number of transactions by
20 each distributor into Huntington-Cabell County, West
21 Virginia during the time frame of the available data?

22 **A.** I was.

23 **Q.** Were you able to identify the number of hydrocodone
24 dose units distributed by each of the defendants into
25 Huntington-Cabell County, West Virginia during the time

1 frame of the available data?

2 **A.** Yes, Your Honor, I was.

3 **Q.** Were you able to identify the number of oxycodone
4 dosage units distributed by each defendant into
5 Huntington-Cabell County, West Virginia during the time
6 frame of the available data?

7 **A.** Yes, I was.

8 **Q.** And did you prepare a slide with your findings?

9 **A.** Yes, I did, Your Honor.

10 **Q.** And would that slide assist you in your testimony
11 today?

12 **A.** Yes, it would.

13 MR. FARRELL: Judge, at this time, we would ask to
14 publish Slide 7.

15 THE COURT: It may be published.

16 BY MR. FARRELL:

17 **Q.** So, would you please take a moment and describe for --
18 to the judge what your findings were regarding the number of
19 transactions, the number of hydrocodone dosage units, and
20 number of oxycodone dosage units for each of the three
21 defendants, AmerisourceBergen, Cardinal Health, and
22 McKesson, during the time frames of the available data?

23 **A.** Your Honor, if we start at the top with
24 AmerisourceBergen and move from left to right, the first
25 column says number of transactions. That's the number of

1 actual sales, the actual distribution. The next column is a
2 number of --

3 THE COURT: Those would be prescriptions?

4 THE WITNESS: Pardon me?

5 THE COURT: Prescriptions?

6 THE WITNESS: No. No. Those would be the sales
7 of the pill bottles, orders from the distributor down to the
8 pharmacy, sir.

9 Q. So, let's take that -- let's take that apart a little
10 bit. When a -- when a pharmacy makes an order or places an
11 order with a distributor, what is the volume or what is it
12 that they're asking to buy?

13 A. Well, medications, but in the case of what I looked at,
14 controlled substances.

15 Q. And so, what's the packaging or what's the -- how is it
16 they buy? Do they buy by the bottle, by the crate, by the
17 box?

18 A. They can buy in multiple ways. They could buy one
19 bottle of a hundred tablets. They could buy ten bottles of
20 a thousand tablets. They could order of any quantity, but
21 an order would be a transaction, a sale.

22 Q. Continue, please.

23 A. The center column, number of hydrocodone, that's the
24 number of hydrocodone tablets that were distributed pursuant
25 to those transactions. And the last column is the number of

1 oxycodone and that would be the number of oxycodone dosage
2 units or tablets that were distributed. The time frame for
3 -- again, for AmerisourceBergen, is 2002 and 2018.

4 **Q.** And for purposes of good order, would you please read
5 into the record the number of transactions for
6 AmerisourceBergen, Cardinal Health and McKesson?

7 **A.** Again, Your Honor, left to right, the number of
8 transactions or sales would be 92,915. Number of
9 hydrocodone tablets, 17,923,260. And the number of
10 oxycodone tablets, 17,187,905.

11 **Q.** And that would be for Cardinal Health?

12 **A.** Yes, it would.

13 **Q.** Okay.

14 **A.** For the time frame of 1996 through 2018.

15 **Q.** Well, I don't have the running transcript, but did we
16 already cover the AmerisourceBergen numbers?

17 **A.** We did.

18 **Q.** Okay. So now, what's left is McKesson. Would you read
19 into the record the transactions and the number of
20 hydrocodone dosage units and the number of oxycodone dosage
21 units from McKesson between 2004 and 2018?

22 **A.** Yeah, Your Honor. Again, the time frame is 2004 to
23 2018 for McKesson. 18,862 transactions. 3,732,930 tablets
24 of hydrocodone. And 3,983,350 tablets of oxycodone.

25 **Q.** Mr. Rafalski, were you able to identify any patterns in

1 the total volume of hydrocodone and oxycodone dosage units
2 distributed by each defendant into Huntington-Cabell County,
3 West Virginia during the time frame of the available data
4 for each?

5 **A.** Yes, I was.

6 **Q.** Were you able to identify the policies and procedures
7 for each defendant applicable during the time frames of the
8 available data?

9 **A.** Yes, I was.

10 **Q.** From the materials that you reviewed, were you able to
11 identify the individuals in charge of Diversion Control for
12 each of the defendants during the time frame of the
13 available data?

14 **A.** Yes, I was, Your Honor.

15 **Q.** And did you prepare a slide for each of the defendants
16 depicting your findings?

17 **A.** I did, Your Honor.

18 **Q.** And would these slides assist you in the presentation
19 of your findings?

20 **A.** Yes, it would.

21 MR. FARRELL: Judge, at this time, I would like to
22 publish Slide 8, which is AmerisourceBergen.

23 THE COURT: It may be published.

24 MR. NICHOLAS: Your Honor, may I interpose an
25 objection to this slide, please? And the objection is that

1 the slide is -- the slide represents something which Mr.
2 McCann prepared, which was never introduced into evidence.
3 And so, this is simply something that another expert
4 prepared that's being published now for this expert to
5 reference, but there's no foundation for it, and I don't
6 think it ought to be used as a demonstrative here.

7 THE COURT: Well, it's based on information that
8 he used in preparing his expert report, isn't it?

9 MR. NICHOLAS: Well, it's based on a slide that
10 Mr. -- that Mr. -- Dr. McCann prepared, but it's unclear
11 whether that slide has been deemed to be admissible. It
12 hasn't been used in this trial up until now. And it's just
13 one expert looking at what another expert said. And I'm not
14 sure that's -- that provides a basis for -- a proper basis
15 for him to rely -- upon which to rely.

16 THE COURT: Mr. Schmidt?

17 MR. SCHMIDT: Yes, Your Honor. I think this issue
18 recurs because it's true for the McKesson version of this
19 slide, as well. The concern we have, just to add to what
20 Mr. Nicholas said, is that we had Dr. McCann either
21 ostensibly to testify on his findings. He did not testify
22 on at least the McKesson version of the slide and I hear Mr.
23 Nicholas saying the same is true for the ABDC version of
24 that slide. Him having foregone that testimony and not
25 introducing these slides to the Court, it is improper for

1 Mr. -- Mr. Rafalski to now come in and sponsor this data
2 which he did not generate himself and which he cannot fairly
3 be cross-examined about himself.

4 THE COURT: Ms. Mainigi, you want to make this
5 unanimous, I see.

6 MS. MAINIGI: Your Honor, I will just join and
7 stay quiet.

8 THE COURT: All right.

9 Mr. Farrell, do you want to respond?

10 MR. FARRELL: Yes, Your Honor. So, two points.
11 Point number one is that Dr. McCann is able to come back and
12 testify and, as you recall, we attempted to bifurcate his
13 testimony between his facts and his opinions. If there's
14 any question about the validity of this, I'm sure they can
15 -- or the accuracy of it, I'm sure that they can -- they can
16 address that with the witness directly.

17 You'll recall that we attempted to winnow down and
18 narrow down the scope of the actual documents we admitted
19 through Dr. McCann, but my ultimate point is that a document
20 does not have to be admissible for an expert to rely upon
21 it, and this is a document that has been disclosed. This is
22 a document that's --

23 THE COURT: Mr. Schmidt?

24 MR. SCHMIDT: All I'll say on the McCann point is
25 we agreed to bifurcation with the understanding that he

1 would present this type of data in round one and then lay
2 the basis for some of these later flagging methodology
3 slides that we haven't yet come to in round two. They don't
4 get a do-over.

5 THE COURT: Mr. Nicholas?

6 MR. NICHOLAS: That was the point I was going to
7 make.

8 MS. MAINIGI: Join.

9 THE COURT: Mr. Ackerman?

10 MR. ACKERMAN: Thank you, Your Honor. Your Honor,
11 Rule 703 does not require evidence. The admitted or even
12 admissible in order for it --

13 THE COURT: Yes. I'm going to cut this short and
14 rely on Rule 703, which the first sentence says an expert
15 may base an opinion on facts or data in the case that the
16 expert has been made aware of or personally observed. He's
17 been aware of this data that comes from Dr. McCann,
18 apparently, or is consistent with what Dr. McCann said and I
19 think that since it's the basis of an expert opinion, it's
20 permissible, and I'm going to overrule the objection and let
21 him go ahead.

22 MR. FARRELL: Thank you, Your Honor.

23 May I approach the screen?

24 THE COURT: You may.

25 BY MR. FARRELL:

1 **Q.** So, Mr. Rafalski, in general, what I want to do is I
2 want to start at the bottom and you'll see that there are
3 names and blocks below the timeline. Will you explain to
4 the Court the -- what you've done here in creating these
5 labels of Zimmerman, Mays and May?

6 **A.** The blocks would represent the policies, the policy
7 changes, and contained within the blocks would be the
8 employees that were responsible during those policy changes
9 or procedure changes by the company.

10 **Q.** And the names that are in the blocks, what does that
11 represent?

12 **A.** The person who was responsible during that time frame
13 of that policy and procedure.

14 **Q.** So, taking your testimony, is this your attempt to
15 delineate the three iterations of the AmerisourceBergen
16 policies and procedures related to SOMS as established
17 earlier in the trial?

18 **A.** Yes, Your Honor.

19 **Q.** And the names that are in the blocks are your attempt
20 to identify the individuals who are in charge of Diversion
21 Control during those time frames?

22 **A.** That's correct, Your Honor.

23 **Q.** All right. Now, looking at the total volume of
24 hydrocodone and oxycodone that was sold by AmerisourceBergen
25 into Huntington-Cabell County, West Virginia, are you able

1 to identify any patterns or trends?

2 **A.** It's pretty apparent, Your Honor, there's a steep
3 upward trend going up through 2010. I'd point out to, Your
4 Honor, you see a steep decline after 2010. That was a
5 change when -- a contract change when the Fruth Pharmacy
6 change shifted distributors from AmerisourceBergen. I
7 think, if the next slide is my Cardinal slide, it would show
8 increase for Cardinal during that time period.

9 **Q.** So, I'm going to draw a box, which I hope to capture
10 the backside of -- starting around 2010. So, explain again,
11 what is it that you're saying is the -- what your findings
12 are of why there was a decline beginning in 2010 by
13 AmerisourceBergen?

14 **A.** A contract shift to the Fruth Pharmacy chain had made a
15 change of distributor. So, they were receiving all their
16 controlled substances from AmerisourceBergen or primarily
17 most of them and that shifted to the Cardinal Health. So,
18 that would -- that would show a sudden decrease in the
19 amount of distribution.

20 **Q.** And so, the measuring stick on the -- I always forget
21 if it's the X axis or the Y axis. We'll call this the X
22 axis. What is the measuring stick on an X axis?

23 **A.** Those would be dosage units.

24 **Q.** And on the Y axis, which is the horizontal one, each of
25 these individual pillars, what unit of time does that

1 represent?

2 **A.** One month.

3 **Q.** And the geographic area for this, can you identify it?

4 **A.** Yes, sir. Cabell County and City of Huntington, West
5 Virginia, Your Honor.

6 **Q.** And which distributor?

7 **A.** AmerisourceBergen.

8 **Q.** So, is -- when you're looking at this, the light blue
9 is what type of prescription opioid?

10 **A.** Hydrocodone, Your Honor. And the dark blue would be
11 oxycodone.

12 **Q.** And so, looking at this graph, is this a visual
13 depiction of the monthly totals by AmerisourceBergen for the
14 entire county and City of Huntington?

15 **A.** Yes, it is, Your Honor.

16 **Q.** Go to the next slide, please. Will you please orient
17 the judge to what Slide number 9 is?

18 **A.** Starting from the bottom up, the three bars at the
19 bottom with the names inside, those would be the three
20 different procedural or policy changes for the company.

21 Moving up to the graph, the light pinkish or light red
22 would be the hydrocodone distribution, tablets listed on the
23 left and the timeline on the bottom. The dark red are the
24 oxycodone.

25 Again, I'd remind you, Your Honor, that in 2010

1 Cardinal changes and becomes the distributor for the Fruth
2 Pharmacy chain. So, that's why you see that sharp increase
3 in 2010.

4 **Q.** And, again, orienting the judge, the X axis or the
5 vertical axis is in what increment?

6 **A.** Dosage units, Your Honor.

7 **Q.** And then on the horizontal timeline, this data goes
8 back to 1996, correct?

9 **A.** Yes, it does.

10 **Q.** And so, this is a longer timeline for Cardinal Health
11 than we have for the other two defendants and that's because
12 we have an expanded amount of transactional data to see,
13 correct?

14 **A.** Yes. That's correct, Your Honor. That's because
15 Cardinal provided more transactional data for the
16 litigation.

17 **Q.** All right. And, again, when we look at the dosage
18 units this is for Cabell and the City of Huntington,
19 correct?

20 **A.** That's correct, Your Honor.

21 **Q.** And this is Cardinal Health; is that right?

22 **A.** Yes, it is.

23 **Q.** All right. Now, I'm also going to note that there is
24 -- seems to be three iterations of the Cardinal Health
25 policy; is that right?

1 **A.** That's correct.

2 **Q.** And who are the names of these individuals?

3 **A.** There's Mr. Reardon for the first bar. Moving left to
4 right, Mr. Mone for the middle bar, and Mr. Cameron on the
5 far right bar.

6 **Q.** Now, do you see any patterns so far between
7 AmerisourceBergen and Cardinal regarding the time frame of
8 the change between the first iteration and the second
9 iteration of the Suspicious Order Monitoring System?

10 **A.** Yes, I do, Your Honor. Both companies would have a
11 change around the 2007-2008 time period.

12 **Q.** Now, let's move on to the next slide, please. And this
13 is McKesson. This is Slide 10. Will you please orient the
14 judge to Slide 10?

15 **A.** Looking at the bottom first, Your Honor, we have two
16 bars there and that would indicate there was only one change
17 in the policy and procedure. The bar on the left, Mr.
18 Hilliard and Mr. Walker, and then around 2008, we have a
19 change in Mr. Gustin and Mr. Oriente.

20 Looking at the graph, just a reminder, the left is
21 dosage units and at the bottom is the timeline. And the
22 gray bars are the hydrocodone. Each bar would be indicative
23 of one month of transactions. And we have the black bars,
24 which are the oxycodone.

25 **Q.** Mr. Rafalski, during the course of your services as an

1 expert witness in this litigation, have you identified in
2 the record any evidence that the defendants monitored the
3 overall volume of hydrocodone and/or oxycodone each
4 distributed into Huntington-Cabell County, West Virginia
5 during the time frames of the available data?

6 **A.** Your Honor, I did not find any indication in the review
7 of the material that I had that they were specifically
8 monitoring distributions into the geographic area of Cabell
9 County or City of Huntington, West Virginia.

10 **Q.** Now, to be clear, what we're talking about is not by
11 pharmacy, but by county or geographic region. What we just
12 walked through with volumes to the county, did you find any
13 evidence of any type of similar monitoring by any of the
14 defendants in this case?

15 **A.** As I answered and I understand the question, no, I did
16 not, Your Honor.

17 **Q.** All right. Now, I hope we have a transition slide as
18 the next slide. Yes. Now, Mr. Rafalski --

19 MR. FARRELL: Judge, we're about to get into a
20 little bit longer block. Should I proceed?

21 THE COURT: Yes, please.

22 MR. FARRELL: Okay.

23 BY MR. FARRELL:

24 **Q.** We talked about AmerisourceBergen and Cardinal Health
25 with the second iteration of their policies and procedures

1 around 2007. Did you find any pattern or trend with the
2 same change or iteration with regard to McKesson?

3 **A.** Yes, I did.

4 **Q.** All right. So, all three companies had a Suspicious
5 Order Monitoring System in place up until somewhere around
6 2007 when there was a change in the policies that you found?

7 **A.** That's correct.

8 **Q.** Okay. Did you find any similarity or pattern amongst
9 the defendants for their policies and procedures for
10 suspicious order monitoring in the pre-2007 era?

11 **A.** I did, Your Honor.

12 **Q.** And have you prepared a slide that depicts a diagram of
13 your understanding of that type of system?

14 **A.** I did, Your Honor, hopefully to make it easier to
15 understand.

16 MR. FARRELL: And, Judge, I'd like to publish
17 Slide 11.

18 THE COURT: Okay. Slide 11? That's 12, isn't it?

19 MR. FARRELL: Yes, 12. Yes, Your Honor. And I
20 would ask and indulge the Court to allow Mr. Rafalski to
21 step down and to walk you through this slide, please.

22 THE COURT: You may do so, sir.

23 THE WITNESS: Simple illustration, Your Honor.

24 This is an order of pills. Here's the pharmacy Rx. They're
25 making an order to the distributor, making an order to the

1 distributor for the purchase of pills. That purchase of
2 pills from the distributor shipped down.

3 As it happened pre-2008, two things would happen. They
4 -- they would ship the pills and report to the DEA ARCOS and
5 this would indicate that they would ship these pills and
6 post-distribution, which meant after the pills had left the
7 distributor, they would submit an excessive purchase report
8 to the DEA. Some companies -- all companies did it on a
9 monthly basis and some companies did it on a daily basis.

10 **Q.** So, Mr. Rafalski, let's start with the ARCOS data.
11 When is the -- when is the ARCOS data reported based on your
12 experience?

13 **A.** Your Honor, it changed a little bit over time, but it's
14 been quarterly or monthly.

15 **Q.** And when we're talking about ARCOS data, please
16 distinguish the ARCOS data from the suspicious order
17 reporting.

18 **A.** The ARCOS data is required by regulation and it only
19 covers the Schedule IIs and the Schedule III narcotics
20 drugs; primarily for this case the hydrocodone.

21 **Q.** Is that what we're calling transactional data?

22 **A.** Yes, it is.

23 **Q.** And then this excessive purchase report, describe for
24 the Court your experience with excessive purchase reports
25 and what you found in the defendants' policies and

1 procedures related to the same.

2 **A.** How the system would work, Your Honor, is they would
3 calculate an average. Some of them would calculate an
4 average nationally or by distributor for a type of business.
5 So, in this case, it would be a pharmacy. They would
6 calculate this average over a 12-month period of data.

7 THE COURT: Mr. Schmidt?

8 MR. SCHMIDT: I didn't mean to interrupt. I'm
9 sorry, Mr. Rafalski.

10 THE WITNESS: That's okay.

11 MR. SCHMIDT: Maybe it was made clear, but I will
12 object as vague as to time frame.

13 THE COURT: Well, I'll sustain the objection. You
14 can ask him about the time frame. I'm not sure it is vague
15 based upon his previous testimony, but you can ask him.

16 MR. FARRELL: I can clarify.

17 MR. SCHMIDT: Thank you.

18 BY MR. FARRELL:

19 **Q.** To be clear, you're describing the systems that were in
20 place by each of the three defendants before 2007 or before
21 each of the defendants made a second iteration change of
22 their existing policies and procedures?

23 MS. MAINIGI: And, Your Honor, my objection on
24 behalf of Cardinal is a little bit different than Mr.
25 Schmidt's. I object to the extent -- I did hear him mention

1 that time period. To the extent this purports to represent
2 Cardinal's system in the pre-2007 time period, I object
3 because it is not accurate. It only reflects one step of a
4 two-step system.

5 MR. SCHMIDT: I think there's inaccuracy as to
6 McKesson, too, and the last question was compound.

7 MR. NICHOLAS: It is true that this slide does not
8 accurately reflect the pre-2007 system so we object on that
9 basis, as well.

10 THE COURT: Well, I think it goes to the weight
11 rather than admissibility of his testimony and you will have
12 ample opportunity to cross examine him on this and I will
13 allow you to go ahead, Mr. Farrell.

14 MR. FARRELL: Thank you. You can take your seat,
15 please.

16 THE WITNESS: Okay. Thank you, Your Honor.

17 BY MR. FARRELL:

18 **Q.** I think I've already distributed copies of this to the
19 parties. Mr. Rafalski, have we identified -- have you
20 identified a particular excessive purchase report that you
21 would like to use as a demonstrative for the Court?

22 **A.** Yes, sir.

23 **Q.** And for the record, this is P-14288ii. I believe it's
24 already admitted in the record. Copies have been provided
25 from counsel.

1 May I approach?

2 THE COURT: Yes.

3 THE WITNESS: Thank you.

4 MR. FARRELL: Would you please bring back up the
5 last slide?

6 You may not want to put it away just yet, Judge. I'm
7 going to make a particular point.

8 THE COURT: Okay.

9 BY MR. FARRELL:

10 Q. So, in general, Mr. Rafalski, we've heard testimony
11 about excessive purchase reports that were submitted by the
12 defendants to the DEA.

13 A. That's correct, Your Honor.

14 Q. And is this one such report?

15 A. Yes, it is, Your Honor.

16 Q. And, in fact, is this one report and, in particular,
17 Cardinal Health from their Wheeling Distribution Center?

18 A. Yes, it is.

19 Q. And is this for one month from one distribution center?

20 A. I believe it is, yes, sir.

21 Q. Okay. And where would this report have been sent?

22 A. It would have been mailed or delivered, but primarily
23 mailed to each of the DEA Offices in the areas. Or for
24 Wheeling, it would have been mailed to the nearest DEA
25 Office that would have covered the Wheeling Distribution

1 Center.

2 **Q.** So, by drawing the timeline here, around 2007 for each
3 of the defendants, it was a little bit different, but
4 between the first and second iteration of their SOMS policy,
5 were each of the defendants in practice receiving orders
6 from a pharmacy, shipping the order, and thereafter
7 reporting the transaction to the ARCOS data, and then
8 publishing these after-the-fact reports based on some metric
9 to the DEA?

10 MR. SCHMIDT: And we'll object. He's not here as
11 a fact witness and his testimony directly contradicts the
12 testimony, for example, of a fact witness that was here just
13 yesterday.

14 MR. FARRELL: Judge, if I may, this is not a
15 proper --

16 THE COURT: Let me hear from Ms. Mainigi.

17 MS. MAINIGI: Your Honor, my objection is that Mr.
18 Farrell -- we've indulged Mr. Farrell in leading this
19 witness because we know everybody wants to get through the
20 testimony, but he's both testifying and leading the witness
21 at this point.

22 THE COURT: Mr. Nicholas?

23 MR. NICHOLAS: I would just join. Join.

24 THE COURT: Well, you can ask him leading
25 questions to get him through this, Mr. Farrell, but don't

1 testify. I mean, don't give him the answer in your
2 question.

3 MR. FARRELL: Yes, Your Honor.

4 THE COURT: Okay.

5 BY MR. FARRELL:

6 Q. So, is what we're -- what I'm holding in my hand from
7 Cardinal Health an exemplar of an after-the-fact report to
8 the DEA?

9 A. That's correct, yes, it is.

10 Q. And have you studied the criteria or have you found
11 evidence in the record of the criteria that Cardinal Health
12 was used -- using pre-2007 for how you wound up on their
13 ILR?

14 A. I did.

15 Q. Okay. I would ask you to turn to Page -- Bates stamp
16 117 on the bottom.

17 A. Okay. I'm there, Your Honor.

18 MR. FARRELL: Judge, what I'm looking at is in the
19 right-hand corner. It says 117. You don't need to actually
20 pull it up. I can put it on the camera, if you would like.

21 THE COURT: Okay.

22 BY MR. FARRELL:

23 Q. So, when you're looking at this document -- let me see
24 if I can get it a little more square.

25 Walk through for us what it is this document is

1 intending to communicate.

2 **A.** Your Honor, this is part of the report, and this is
3 specific for a customer. So, a little bit down where you
4 see the little dots it starts -- I'll take that particular
5 customer. Customer number, Medicine Shoppe number 290,
6 Huntington. It has the address, 2402 Adams, Huntington,
7 West Virginia. That would be the customer that's purchasing
8 these products from Cardinal Health.

9 **Q.** And what was the run date or the date that this was
10 report was run?

11 **A.** May 6th of 2007.

12 **Q.** And what is the time frame that this report is
13 intending to cover?

14 **A.** April of 2007.

15 **Q.** All right. And so, when you look at the report down at
16 the bottom right-hand corner, do you see this ingredient
17 limit?

18 **A.** I do.

19 **Q.** Total grams. Do you see that here, total grams?

20 **A.** I do.

21 **Q.** Through -- through your review, have you been able to
22 determine what an ingredient limit is in Cardinal Health's
23 program?

24 **A.** I did.

25 **Q.** What is an ingredient limit?

1 **A.** So, that's the -- the actual trigger or threshold that
2 they have calculated. If you look below April, 2007, Your
3 Honor, you will see the factor used as four and for Cardinal
4 Health they would create an average for the distribution
5 center of the distribution of oxycodone products. They'd go
6 back 12 months and create an average and then they would
7 times it by four. And that four would be the ingredient
8 limit number at the very bottom, 104.82.816 grams. So, that
9 essentially is four times the average of the pharmacies that
10 they -- they took into consideration from that distributor.

11 **Q.** So, to be clear, every month Cardinal Health was
12 running this document and they were taking the average
13 retail pharmacy from that distribution center, they were
14 multiplying it by --

15 THE COURT: Ms. Mainigi?

16 MS. MAINIGI: Mr. -- Mr. Farrell is testifying at
17 this point.

18 MR. FARRELL: I'm trying --

19 MS. MAINIGI: And summarizing.

20 MR. FARRELL: I'm summarizing, yes, Judge.

21 THE COURT: Well, I'm going to overrule the
22 objection and let you do it. I don't think this is
23 misleading and we're getting him through his testimony and
24 it's complicated and I need to understand it so I'm going to
25 let you do it, Mr. Farrell.

1 MR. FARRELL: Thank you.

2 BY MR. FARRELL:

3 Q. So, Cardinal Health on a monthly basis, and this would
4 be performed in May, but for the April transactions, would
5 take the average from the retail pharmacies serviced by that
6 distribution center and multiply it by four, correct?

7 A. That's correct.

8 Q. And, in this instance, that means 140 grams would be
9 the ingredient limit, which is four times the average
10 pharmacy the Wheeling Distribution Center was servicing?

11 A. That's correct, Your Honor. Your Honor, the total --
12 the grams column, do you -- do you need me to explain what
13 those are to you?

14 MS. MAINIGI: Perhaps Mr. Farrell can ask a
15 question.

16 THE WITNESS: Oh, sorry.

17 THE COURT: Yes. I --

18 MR. FARRELL: Yes, sir. Yes, sir.

19 THE COURT: Go ahead.

20 THE WITNESS: I'm sorry, Your Honor.

21 BY MR. FARRELL:

22 Q. So, before we get there, what we have -- what would you
23 describe this ingredient limit, this 104 grams, what does it
24 mean?

25 A. The 104 grams is the actual active narcotic amount

1 that's contained in four times the average, 12-month
2 average.

3 **Q.** And so --

4 THE COURT: Let me interrupt you. I'm unclear as
5 to what an excessive purchase is and how -- what the basis
6 is for determining if a purchase is excessive. Are you
7 getting there?

8 MR. FARRELL: I'm trying to, yes, Your Honor.

9 THE COURT: Okay.

10 BY MR. FARRELL:

11 **Q.** So, the ingredient limit of 104 grams is four times the
12 average of the retail pharmacies for that month for this
13 distribution center, correct?

14 **A.** That's correct.

15 **Q.** And was Cardinal Health using that as a benchmark to
16 determine what an excessive order was?

17 **A.** Yes. It would monitor the purchases of each of its
18 customers and any customer that exceeded that 104.82816
19 would fall onto the list.

20 **Q.** Now, this particular customer in Huntington, West
21 Virginia and for oxycodone-based drug, you'll see here a
22 list of all of the orders from that month from The Medicine
23 Shoppe to Cardinal Health, correct?

24 **A.** Yes.

25 **Q.** And what type -- can you walk through briefly the types

1 of drugs that were ordered here?

2 **A.** This is specific for oxycodone products, Your Honor.
3 So, every product that's on this list is -- contains
4 oxycodone. The first one, Roxicet, those are combination
5 drugs, five milligrams of oxycodone and 325 milligrams of
6 acetaminophen.

7 You fall down below the next three. Those are
8 OxyContin drugs. Those are -- contain just oxycodone. And
9 so, the 80 milligrams would be the active ingredient of
10 oxycodone in each pill.

11 **Q.** So, let's -- let's stop right there for a second and
12 give just one example. So, if we're looking at one
13 particular transaction here, this would be a quantity of
14 four, 100 tabs of Oxy 80s, correct?

15 **A.** Yes.

16 **Q.** So, that's a particular request or transaction for 400
17 oxy 80 tabs?

18 **A.** That's correct, Your Honor.

19 **Q.** Now, in the far right-hand corner what Cardinal Health
20 has done is they've taken the active ingredient for each of
21 these orders and then totalled them for a customer total; is
22 that right?

23 **A.** That's correct.

24 **Q.** So, in this month of April, 2007, Cardinal Health
25 shipped to The Medicine Shoppe 157 grams of oxycodone,

1 correct?

2 **A.** That's correct.

3 **Q.** And after shipping it, it then reported to the DEA and
4 this report that that month exceeded the cap of 104 grams?

5 **A.** Yes. The 104 grams, Your Honor, didn't stop the
6 distribution. It was just the measure of when to place
7 these customers onto this list.

8 THE COURT: I need to stop you. My realtime has
9 gone awry.

10 COURT REPORTER: Can I have one minute, please?

11 THE COURT: Yes.

12 (Pause)

13 COURT REPORTER: Is it on now?

14 THE COURT: Yes.

15 COURT REPORTER: I think something -- it's sorted
16 out. Okay.

17 BY MR. FARRELL:

18 **Q.** So, using --

19 MR. FARRELL: I'm sorry, Judge. May I continue?

20 THE COURT: Yes.

21 BY MR. FARRELL:

22 **Q.** So, using this as an exemplar, The Medicine Shoppe
23 would be the pharmacy, correct?

24 **A.** That's correct.

25 **Q.** And it made orders from Cardinal Health?

1 **A.** That's correct.

2 **Q.** And all of those orders got shipped that are on that
3 list?

4 **A.** That's correct.

5 **Q.** Those orders, either on a monthly or quarterly basis,
6 the transactions would be reported to the ARCOS database,
7 correct?

8 **A.** Yes.

9 **Q.** And because the orders for that month from this
10 pharmacy exceeded four times the average, this pharmacy got
11 included in an excessive purchase report sent to the DEA?

12 **A.** That's a correct statement, Your Honor.

13 **Q.** And so, whether you call it an ingredient limit report
14 or an excessive purchase report, the defendants pre-2007
15 were identifying some type of threshold that if you exceeded
16 it, got reported to the DEA?

17 THE COURT: Mr. Schmidt?

18 MR. SCHMIDT: And, Your Honor, he's giving very
19 specific testimony about Cardinal. If he's going to make
20 these sweeping assertions, he should give the similar
21 testimony about McKesson, and I assume ABDC is taking the
22 same view.

23 MS. MAINIGI: And, Your Honor, I have a continuing
24 objection because his testimony seems to reflect that
25 there's only a one-step process and there was a two-step

1 process.

2 MR. FARRELL: Judge, if I may, these are --

3 THE COURT: Let me hear from Mr. Nicholas before
4 that.

5 You go ahead.

6 MR. NICHOLAS: I just join in both objections as
7 are articulated. I don't need to re-state them.

8 THE COURT: Mr. Farrell?

9 MR. FARRELL: These are improper objections, Your
10 Honor. To stand up and say that I'm wrong is not the
11 appropriate time for this. They have the opportunity to get
12 up and cross and ask these questions.

13 THE COURT: Yeah. I'll overrule the objection.
14 Let's press on.

15 BY MR. FARRELL:

16 **Q.** Mr. Rafalski, sometime around the year 2007 from your
17 prior testimony each of the three distributors changed the
18 way in which they were performing their suspicious order
19 monitoring, correct?

20 **A.** That's correct, Your Honor.

21 **Q.** Have you prepared a diagram that illustrates the design
22 of the system used or the common design features used by
23 each of the three defendants after 2007?

24 **A.** Yes, I have.

25 MR. FARRELL: And, Judge, at this time what I

1 would like to do is I would like to publish the second half
2 of this slide and ask Mr. Rafalski to step down and describe
3 it for the Court.

4 THE COURT: You may do so.

5 THE WITNESS: Thank you, Your Honor.

6 Ready, Your Honor?

7 MR. FARRELL: Hold on.

8 THE WITNESS: As -- as the previous, this is the
9 pharmacy and this is an order that's transmitted to the
10 distributor for purchase of controlled substances. Upon --
11 prior to the shipment, we now have the change in the system.
12 This is a Suspicious Order Monitoring System. You can kind
13 of characterize it as a little computer or little box.
14 Built into that is a way that they monitor the flow of drugs
15 and calculate the amounts and this makes a decision.

16 There's a trigger or threshold that's set inside of
17 this system and if it's below the trigger of the threshold,
18 the purchase flows through, goes to ship, and the -- and the
19 company also reports to ARCOS.

20 If it -- if it triggers the system, in other words,
21 like the ingredient limit report, if it hits that threshold,
22 it stops the order and it now holds it as part of this
23 system.

24 BY MR. FARRELL:

25 Q. Now, Mr. Rafalski, once the system holds an order, how

1 -- what is the design process that's supposed to follow?

2 **A.** So, when we talk about a suspicious order, Your Honor,
3 the suspicion is that this order could be diverted. In
4 other words, it could fall into illicit hands. The
5 maintenance of effective controls to prevent diversion is
6 what's the key issue here in that the company has -- has --
7 takes this held order and they make a decision on whether
8 they're going to ship it.

9 Part of that decision process is commonly called due
10 diligence. It's an internal investigation where they look
11 at some internal information and facts and circumstances,
12 take some action as warranted, and the company would make a
13 decision.

14 If they believe that this suspicion is dispelled, that
15 dispels the potential for diversion, then that order would
16 flow down to the customer and also be reported to ARCOS.

17 If, in fact, they conduct this investigation and they
18 can't clear or dispel the suspicion, then that order would
19 be blocked and cancelled and it would be reported to the
20 DEA.

21 MR. FARRELL: Thank you. Take your seat, please.

22 MS. MAINIGI: Your Honor, my objection is just the
23 characterization of the testimony is on its face different
24 from the characterization of the chart. There is the
25 shipped order and the held order. At that point, there's no

1 indication of suspicion. The suspicious order reporting
2 comes later.

3 THE COURT: I will overrule the objection. You
4 have an opportunity to cross him on this and I think it's
5 more appropriate to cross him on that than it is to exclude
6 it entirely. So, overruled.

7 BY MR. FARRELL:

8 Q. So, Mr. Rafalski, we're going to talk in more detail
9 about this, but I am going to jump ahead and foreshadow
10 another issue. Have you been able to discern from the
11 actual policies and procedures for the defendants what
12 should happen once the system is triggered for future
13 orders?

14 A. They should be held, Your Honor, stopped.

15 Q. Now, what that means is, is that a -- I'm asking you in
16 abstract. A single order comes in to the distributor and it
17 flows down to the computer system. And that computer system
18 has some type of threshold, or algorithm, or trigger and
19 let's say that that trigger happens and it institutes the
20 process, whatever it may be, to hold that order.

21 If due diligence takes, say, a month, what do the
22 policies and procedures from the defendants say should
23 happen to all subsequent orders until the initial order
24 finishes the due diligence process?

25 THE WITNESS: Your Honor --

1 MR. SCHMIDT: I'm sorry. I have to object. If I
2 heard the question right, it's what do our policies say.
3 He's not here to interpret what our policies say. If he
4 wants to ask what the duty is as he understands it, he can
5 say that and we can cross examine him on it, but I don't
6 think he's here to say what our policies say.

7 THE COURT: Sustained.

8 BY MR. FARRELL:

9 Q. I'm going to be careful with this question. Once a
10 suspicious order is flagged, what is the duty of the
11 defendants regarding all future orders that are placed by
12 the same customer?

13 A. Specifically, to the family of the drugs that are held,
14 they should all be stopped.

15 THE COURT: Even if they're just a tiny little
16 order?

17 THE WITNESS: Just a small, tiny little order,
18 Your Honor.

19 MS. MAINIGI: And, Your Honor, my objection is I
20 would like to clarify for the record that that's his
21 personal view. He's not trying to state what the law is.

22 MR. NICHOLAS: I have to add, Your Honor, that the
23 way this was described by Mr. Farrell and the question, it
24 was suggested that at this stage these are suspicious
25 orders. These are not suspicious orders at this stage of

1 the game. These are -- these are flagged orders, but they
2 are not suspicious orders, and that's an important
3 distinction and I think the record has to be clear on that.

4 THE COURT: Well, these are things that can be
5 cleared up on cross, it seems to me, and I'm going to allow
6 you to go ahead. Overruled.

7 Go ahead, Mr. Farrell.

8 MR. FARRELL: All right.

9 BY MR. FARRELL:

10 Q. So, in your analysis did you rely upon the fact that a
11 triggering order should block all future orders of the same
12 drug type?

13 A. Yes.

14 Q. And if the system is working as designed, there's an
15 immediate process to be able to determine whether to ship or
16 block?

17 A. That's correct, Your Honor.

18 Q. And if you ship, that means you have cleared the
19 suspicion that it's being diverted, correct?

20 A. That's correct, Your Honor.

21 Q. And if you block it, that means you're suspicious these
22 pills are getting diverted?

23 A. You -- you've conducted your due diligence and you
24 can't dispel the suspicion, the potential for diversion,
25 Your Honor.

1 Q. Now, to be clear --

2 THE COURT: And your testimony is that that was
3 built into the system here that all three of these
4 defendants had in place?

5 THE WITNESS: Yes, sir. Starting between 2007 and
6 2008, they all designed a system to do exactly that.

7 THE COURT: But that was your understanding of
8 what the system was and what it was designed to do?

9 THE WITNESS: In general terms, yes, sir.

10 THE COURT: Go ahead, Mr. Farrell.

11 BY MR. FARRELL:

12 Q. So, the system is designed to have a trigger, correct?

13 A. Yes.

14 Q. Now, if you set that trigger at ten pills a month,
15 based on your experience, how many times will this system go
16 ding, ding, ding?

17 A. A lot because they don't sell pills in -- ten pills.
18 So, usually, the smallest amount is a hundred, generally
19 speaking. There's some drugs that are a little smaller.
20 So, every transaction would go ding, ding, ding, Your Honor.

21 Q. And if you set this trigger at 40,000 pills a month,
22 how many times would the system go ding, ding, ding?

23 A. It wouldn't until you bought 40,000 and 100 pills, Your
24 Honor.

25 Q. And so, based on your experience -- well, no. I'm

1 going to back up a minute. We'll circle back to that.

2 So, what we're going to do now is we're going to talk
3 about the different triggers that you have seen from your
4 investigations, as well as from your review of this case.

5 Before we get there, just to be clear, once the system
6 triggers, the order should be held until due diligence can
7 make sure it's not being diverted, correct?

8 **A.** Yes. Yes, Your Honor, that's my opinion.

9 MR. FARRELL: Judge, this is a bigger block that
10 we're about to go into, if you'd want to take a break.

11 THE COURT: Well, does anybody need a break?
12 We've already taken one this morning.

13 MR. FARRELL: I'm good.

14 THE COURT: Let's go forward full speed ahead, Mr.
15 Farrell.

16 MR. FARRELL: Yes, sir.

17 All right. Let's go to the next slide, please. Wait,
18 no. Don't do that.

19 BY MR. FARRELL:

20 **Q.** Mr. Rafalski --

21 **A.** Yes, Mr. Farrell?

22 **Q.** Have you identified methodologies by which registrants
23 have used or you have experienced or seen as a triggering
24 mechanism for their SOMS?

25 **A.** Yes, I have.

1 **Q.** And have you prepared a slide that identifies the
2 various methodologies that you have employed when reviewing
3 data?

4 **A.** I have, Your Honor.

5 **Q.** And would looking at that slide assist you in your
6 testimony with the Court?

7 **A.** Yes, it would.

8 MR. FARRELL: Judge, if permitted, I would like to
9 publish slide 14.

10 Okay. I know that this is --this is the slog. And
11 so, Judge, I'm going to try to be very methodical, but this
12 is -- this is a technical portion.

13 THE COURT: All right.

14 BY MR. FARRELL:

15 **Q.** Mr. Rafalski, is there one particular golden rule on
16 what the trigger should be?

17 **A.** No, Your Honor.

18 **Q.** Okay. Describe for the judge what guidance is
19 available out there for how high to set the trigger or how
20 low to set the trigger.

21 **A.** Well, that determination, Your Honor, is for the
22 company, the registrant. The regulation, the suspicious
23 order monitoring regulation, speaks to it and it says that
24 they would typically be trying to identify orders of unusual
25 size, deviating substantially from a normal pattern or an

1 unusual frequency.

2 In the cases of these systems, they're only looking at
3 the volume and it's a critical decision to try to determine
4 for each customer what would be the usual amount of drugs
5 that they were purchasing.

6 **Q.** Now, have you been privy to the actual computer code
7 algorithm used by each of the defendants inside their
8 suspicious order monitoring systems?

9 **A.** It was not provided as part of the litigation, Your
10 Honor.

11 **Q.** But based on your experience as a DEA investigator,
12 have you been able to generally replicate what that number
13 should look like?

14 **A.** I'm not sure I understand your question, what -- what
15 the numbers should look like.

16 **Q.** The threshold.

17 **A.** It would be calculated to depend on what the system is
18 or how they designed the system.

19 **Q.** And have you been able to discern how each of these
20 systems have been generally designed?

21 **A.** Yes, I have.

22 **Q.** Now, to be clear, how many different systems are
23 possible?

24 **A.** It would be a huge number, Your Honor, because you have
25 to take in consideration the range of types of registrants

1 that could purchase. So, if you're distributing drugs to a
2 hospital, you could be looking at a large number. You could
3 be distributing drugs to a veterinarian, a veterinarian's
4 office. He would have the ability -- he or she would have
5 the ability to purchase drugs.

6 So, there, you would be looking at a smaller amount and
7 a smaller type, a different type. Veterinarians wouldn't
8 have use for drugs like Adderall. So, it's my belief that
9 the regulation, the way it is, allows the flexibility for a
10 registrant to desire a -- design a system to meet their
11 business needs and to service their customers.

12 **Q.** So, this gets back to purpose. When we're designing
13 this trigger, when we're designing this function, this
14 threshold, this algorithm at the stage of the transaction,
15 what is it that we're trying to flag? What's the purpose of
16 flagging certain orders?

17 **A.** We're trying to identify an order, Your Honor, that has
18 a suspicion of diversion, that is outside of what's normal
19 and what's usual.

20 **Q.** So, looking at this, have you identified several
21 different methodologies and then -- and then applied those
22 methodologies to the data?

23 **A.** I have.

24 **Q.** And so, in general, will you identify for the record
25 what each of these, A, B, C, D, E and F are? We're talking

1 a hundred thousand feet looking at it because we're going to
2 walk through each of them.

3 **A.** The first one, Your Honor, is maximum monthly trailing
4 six-month threshold. That is the system that was used by
5 Masters Pharmaceutical that was discussed in the DC
6 appellate ruling.

7 B, that's a -- the trailing six-month maximum monthly
8 fixed after first triggered threshold. That's a repeat of
9 the Masters system, but used in my review, it's going to be
10 used a little differently. I think we're going to explain
11 that.

12 The third one, C, twice trailing 12-month average,
13 that's based on the Mallinckrodt system that was in the
14 litigation in one of the other cases.

15 D, three times the 12-month average is ABDC and
16 Cardinal. Was used at one of the systems that they used in
17 the time periods I showed you earlier.

18 MS. MAINIGI: Objection, Your Honor, to the
19 testimony. That is outside the scope of his report. It was
20 not identified. His number -- or his letter D methodology
21 was not disclosed in his report as identified with Cardinal.

22 THE COURT: Mr. Farrell?

23 MR. FARRELL: Judge, I'm not quite sure how to
24 respond to that. It's an enormous report. But I think it
25 was undisputed that Cardinal was running a three-times

1 multiplier.

2 MS. MAINIGI: We looked -- we got these
3 demonstratives at midnight, Your Honor, and we looked back
4 at the report. It was not identified with Cardinal.

5 MR. FARRELL: Judge, I believe the record and the
6 testimony will indicate that Cardinal Health's witnesses
7 testified repeatedly that they were using a three times
8 12-month average methodology, but it doesn't matter. These
9 are -- these are attempts by Mr. Rafalski to run whatever
10 metric they want to run to show that the transactions should
11 have lit up like a Christmas tree.

12 THE COURT: Well, I'm -- go ahead. I'm sorry.

13 MS. MAINIGI: No. I'm sorry, Your Honor. I -- I
14 don't want to get into an argument about this, Your Honor,
15 because I know you want to move on, but I'm just noting that
16 for the record. It is completely outside of the scope of
17 the report. I know Your Honor has no ability to confirm
18 that right now.

19 THE COURT: I'm going to overrule your objection
20 and your objection will, of course, be preserved for the
21 record.

22 And you can go ahead, Mr. Farrell.

23 MR. FARRELL: All right.

24 BY MR. FARRELL:

25 Q. And so, to move through quickly, E and F are also

1 different types of algorithms or metrics that you're
2 attempting to replicate and run against certain datasets,
3 agreed?

4 **A.** Datasets for each of the defendants, yes, sir, Mr.
5 Farrell.

6 MR. FARRELL: So, I'm going to attempt to do this,
7 Judge, and I will abandon it if it is -- turns out to be a
8 mess.

9 But let's go to the next slide.

10 BY MR. FARRELL:

11 **Q.** So, what we have here is we have a fictional
12 theoretical monthly distribution that escalates over time.

13 **A.** That's correct, Your Honor.

14 **Q.** And I have asked for you to explain each of the
15 methodologies based upon a fictional setting so the judge
16 can understand how each methodology works.

17 So, let's start with A, which is the Masters test,
18 maximum monthly trailing six-month threshold. Would you
19 explain to the judge how that is supposed to work in theory?

20 **A.** Your Honor, if you look down at the bottom of the
21 chart, it starts at number one through number six. Each
22 number there, the bar would represent the number of pills
23 that are distributed for each of those months.

24 At the end of the sixth month, the system would look
25 back and, while it's monitoring the seven-month, if that

1 month exceeded the highest month in the previous six months,
2 it would stop that distribution.

3 **Q.** All right. So, what I'm attempting to do is I'm
4 attempting to follow you along. It looks backwards six
5 months?

6 **A.** That's correct.

7 **Q.** And it identifies the highest amount of any prior six
8 months?

9 **A.** That's correct.

10 **Q.** And that creates the cap, correct?

11 **A.** Yes. That creates a trigger or a threshold.

12 **Q.** Now, in this theoretical abstract in month seven you
13 will see there's just a little bit in excess, right?

14 **A.** That's correct.

15 **Q.** This would be the system, as designed, its objective
16 would just trigger that there is a hold being placed because
17 the highest amount in the past six months has been exceeded,
18 correct?

19 **A.** That's correct, Your Honor.

20 **Q.** And what should happen based on the design once the
21 trigger happens in month seven?

22 **A.** Should stop, stop the distribution.

23 **Q.** Until what?

24 **A.** Until you clear that suspicion, due diligence is
25 applied. And, Your Honor, just for clarification, it

1 doesn't wait until the end of the seventh month. If at any
2 time in that month it exceeds that amount, it will stop it.

3 **Q.** Now, under Scenario A, let's assume that no due
4 diligence is done and that the alarm, for lack of a better
5 word, the fire alarm, never gets turned off.

6 **A.** Okay.

7 **Q.** What should happen with all of the subsequent orders
8 until the fire alarm is turned off?

9 **A.** They should not be shipped.

10 **Q.** Okay. Now, under B, tell the judge what the difference
11 between A and B is.

12 **A.** Your Honor, this looks -- looks back the same way as I
13 just described. So, on this particular chart everything
14 would look the same. The trigger would stop in the seventh
15 month. After the seventh month that would set a fixed
16 threshold that would run across all future transactions.

17 **Q.** Now, under Methodology B, my understanding is, is that
18 until there's due diligence, there would be a cap placed at
19 the highest level of the last six months, correct?

20 **A.** That's how the methodology was applied.

21 **Q.** So, instead of blocking all of the orders until due
22 diligence resolves, the only thing that it blocks is the
23 orders in excess of the thresholds; is that right?

24 THE COURT: Mr. Schmidt?

25 MR. SCHMIDT: This is pure testimony, Your Honor,

1 and as an illustration of that, the question want to go --

2 COURT REPORTER: I'm sorry. Can you speak up for
3 me a little?

4 MR. SCHMIDT: Yeah, of course. And I'm sorry. I
5 had the microphone off.

6 This is pure testimony, Your Honor, and as an example
7 of that, he led his witness into misstating his own
8 methodology in the last question. I think he mixed up
9 Methodology B and Methodology A.

10 THE COURT: Well, I'm going to overrule the
11 objection. I'm just trying to understand this.

12 And go ahead, Mr. Farrell.

13 MR. FARRELL:

14 Q. All right. So, under Methodology A, we're looking at
15 the last six months. And then, in present time, we live in
16 month seven. Right?

17 A. Yes.

18 Q. So, in month seven, the way this system worked is it
19 would look at the past six months?

20 THE COURT: You're going through what you've
21 already --

22 MR. FARRELL: I'm sorry.

23 THE COURT: -- taken him through, Mr. Farrell.

24 MR. FARRELL: I was taking a cue that you were
25 asking for more explanation.

1 THE COURT: Well, I think I've -- I've got it so
2 far. So, let's move on to the next step.

3 MR. FARRELL: Yes, Your Honor. I apologize.

4 BY MR. FARRELL:

5 Q. So, now let's move on to C, twice trailing 12-month.

6 A. Can I make a correction on the previous one?

7 Q. Yes.

8 A. On the B methodology? So, it doesn't -- it doesn't
9 stop --

10 MR. SCHMIDT: I didn't mean to interrupt.

11 THE COURT: Yeah. Go ahead.

12 MR. SCHMIDT: But I would like to say something
13 after.

14 THE WITNESS: It doesn't cut all of those orders
15 and only ship that amount. It would only ship the orders
16 that didn't exceed that red line.

17 THE COURT: Okay, Mr. Schmidt.

18 MR. SCHMIDT: And that's what I flagged, Your
19 Honor. That's my concern with the leading. He actually led
20 him into improper testimony that had I not objected would
21 stand on the record.

22 MR. FARRELL: Well, Judge, I would think that his
23 objection is what led him into this.

24 THE COURT: Well, I'm going to overrule the
25 objection at this point and you can go ahead.

1 MR. FARRELL: All right.

2 BY MR. FARRELL:

3 Q. So, twice trailing 12 months, please walk the judge
4 through how that type of methodology would be employed.

5 A. Your Honor, if we go back to the chart and you see the
6 transaction that would flow from month 1 to month 12, we get
7 to month 12 and that's the trailing 12 months. So the
8 system would look back to 12 months. It would take each of
9 the monthly transactions and create an average. And then it
10 would take two times of that average.

11 Generally, in this kind of an illustration, that would
12 be right around six, month 6 approximately. So, it would be
13 two times of month six.

14 Q. So, backing up, the 12-month average, average of what?

15 A. Distribution of pills. Each one of those bars
16 represent the number of pills that go out each month but,
17 Your Honor, this is -- it's trailing 12 months so --

18 Q. Mr. Rafalski, hold on a second. Average of that
19 customer? Average of that region? Average of that nation?
20 What is it an average of?

21 A. It depends how they -- how they set it, how the company
22 sets it. They could set it by groups of pharmacies,
23 individual pharmacies. And how we applied it, or how I
24 applied it, actually, in the methodology was it was applied
25 -- in one segment of time of the analysis, it was the State

1 of West Virginia transaction average. And there was a
2 section during ARCOS period where it was the national
3 average. And it would be two times the national average, if
4 that answers your question --

5 **Q.** I think so.

6 **A.** -- about the methodology or about the example.

7 **Q.** Now, when we say the word trailing, explain to the
8 judge what that terminology, that lexicon means, trailing?

9 **A.** So, as the transactions, Your Honor, move left to
10 right, when it goes to month 13, month 1 just falls off and
11 it recalculates the average. And it would continue to do
12 that function system from that point on.

13 **Q.** Now, under D, three times 12-month average, how does
14 that work?

15 **A.** It essentially is the same description I gave you, Your
16 Honor, for the -- for the previous, the two times, but this
17 time it would go three times the average.

18 And, Your Honor, just for the illustration, the line
19 wouldn't go straight across because, as the next month hit,
20 as this chart is illustrated, it would bump up a little bit
21 each time.

22 **Q.** All right. Now, let's go to E, maximum 8,000 dosage
23 units. Tell me how putting a threshold cap should work.

24 **A.** That's what this describes. In this case, there was a
25 decision that the maximum amount of drugs that could be

1 shipped on a monthly basis would be 8,000.

2 THE COURT: To each individual customer?

3 THE WITNESS: Yes.

4 BY MR. FARRELL:

5 Q. Per month? Per day?

6 A. Per month.

7 Q. Per month? And so, if this is the 8,000 on our bar
8 graph, what happens to orders in excess of 8,000?

9 A. They would be stopped by the system.

10 Q. Unless what?

11 A. They would conduct due diligence and clear the order of
12 the suspicion of diversion and then it would continue on.

13 Q. And what about raising the threshold above 8,000, what
14 would be the expectation to raise a base hold threshold?

15 A. Specific to a customer, Your Honor, I would expect to
16 see a pretty in-depth evaluation to increase a threshold,
17 some reasons and justification to make that change. But
18 it's a possible -- it's a good thing to happen within a
19 system if there needs to be an increase of distribution.

20 Q. Now, the final one that we're going to talk about is
21 letter F, and I think we have to go to the next slide to
22 explain it. Tell the judge what F is, the sixth version.

23 A. The sixth version is -- it's referred to sometimes as
24 the pickers and packers. So, inside of the cage and the
25 vault area at the distributors, they hang a list. And the

1 list provides the amount of drugs that can be shipped out in
2 one order.

3 So, for example, say arbitrary 500 dosage units of
4 oxycodone. When the employees in the -- in the distribution
5 center are handling or filling an order or picking an order,
6 that's why they call them pickers and packers, if that order
7 exceeds 500 dosage units, then they -- I take it they stop
8 the order.

9 **Q.** Now, let me step real quick. When we're talk about
10 this final methodology, are we talking about monthly, weekly
11 or daily cap?

12 **A.** It says a daily. It would be a daily order.

13 **Q.** So, every single day, there is a maximum amount of
14 pills that the pickers and checkers can put -- can fill on
15 behalf of a customer, correct?

16 **A.** Yes. Below the amount, it's just free to go. Above
17 the amount, they --

18 **Q.** How did you determine what those amounts should be in
19 this case?

20 **A.** That was determined by using one of the defendants',
21 their system, those amounts.

22 **Q.** Okay. Now, were you able to take these methodologies,
23 A, B, C, D, E and F, and run them against the transactional
24 data provided by the defendants?

25 **A.** I was.

1 **Q.** And using each of those methodologies, were you able to
2 make findings as to what flags should have happened and
3 which order should have been blocked?

4 **A.** Yes, I was, Your Honor. Just -- just for technical
5 purposes, I didn't have the capabilities of a computer to do
6 that. That was what Mr. McCann did, but I communicated my
7 request for Mr. McCann to produce that.

8 MR. FARRELL: So, bring up Slide 17, please.

9 BY MR. FARRELL:

10 **Q.** Mr. Rafalski, is this a depiction of your findings
11 running methodology A against the defendants' data?

12 **A.** Yes, it is, Your Honor.

13 **Q.** Okay. So, this is the -- under A, this is the Masters
14 test that once the first order is flagged, it blocks
15 everything after it, correct?

16 **A.** That's correct.

17 **Q.** And under that assessment, what were your findings
18 regarding oxycodone and hydrocodone for AmerisourceBergen,
19 Cardinal and McKesson?

20 **A.** Your Honor, the top for AmerisourceBergen, reading left
21 to right, the flagged orders of oxycodone in dosage units
22 was 11,610,920. With a total amount of 90.6 percent of the
23 total dosage units.

24 The flagged orders of hydrocodone in dosage units is
25 20,621,360, or 91.1 percent of total dosage units.

1 Dropping down to Cardinal Health, 15,997,400, or
2 93.1 percent of the total dosage units.

3 And 14,795,350, or 82.5 percent of the dosage units.

4 And, finally, McKesson at the bottom, 3,501,970 dosage
5 units, or 87.9 percent of the total dosage units.

6 And for hydrocodone, 3,261,250, or 87.4 percent.

7 **Q.** Now, Mr. Rafalski, am I correct that this is what
8 should have been blocked by the defendants assuming no due
9 diligence was performed?

10 **A.** Yes, sir. Another way of stating when the first block
11 occurred and the suspicion was not clear, the suspicion of
12 diversion wasn't dispelled, all subsequent ones.

13 **Q.** So, to be clear, under A, the system was designed to
14 set off a fire alarm and if that fire alarm never got turned
15 off, the result would be as you would see on this screen, a
16 substantial volume of pills would never have been shipped
17 into Huntington-Cabell County, West Virginia?

18 **A.** That's a correct statement, Your Honor.

19 **Q.** Okay. Now, under Scenario A -- well, we'll get back to
20 that. Let's go to B. Now, under B, it doesn't block all of
21 the subsequent orders, but it places a cap that blocks
22 everything in excess of the cap, correct?

23 **A.** That's correct. That would be the first time the
24 systems trigger. It would be fixed.

25 **Q.** And under Scenario B, what are your findings regarding

1 oxycodone dosage units and hydrocodone dosage units for
2 AmerisourceBergen, Cardinal and McKesson?

3 **A.** Your Honor, for AmerisourceBergen, the flagged orders
4 of oxycodone in dosage units 3,763,580, or 29.4 percent.

5 Flagged orders of hydrocodone, 5,616,380, or 24.8
6 percent.

7 Dropping down to Cardinal Health, 11,325,200, or
8 65.9 percent.

9 7,252,580, or 40.5 percent, that's of dosage units.

10 And McKesson, 805,300 dosage units, 20.2 percent. Or
11 2,390,800, or 64 percent of hydrocodone tablets.

12 **Q.** Now, let's go to C, which is a different methodology,
13 and this is the trailing -- twice trailing 12-month average
14 or, in general, an average over 12 months multiplied by two.
15 When you run that methodology, what were your findings?

16 **A.** As stated on the screen, Your Honor, AmerisourceBergen,
17 10,477,680 dosage units, or 81.8 percent.

18 Flagged orders of hydrocodone, 18,877,140, or
19 83.4 percent.

20 Cardinal Health, 14 -- 14,011,880, 81.5 percent.

21 Hydrocodone, 16,593,780, 92.6 percent.

22 Dropping down to McKesson in the bottom, Your Honor,
23 2,405,620, 60.4 percent for oxycodone and for hydrocodone,
24 2,362,420, 63.3 percent, sir.

25 **Q.** And, Judge, we can continue to read into the record or

1 I would submit Slides -- I think they're 17, 18, 19, 20, 21
2 and 22 for the record as evidence.

3 MR. SCHMIDT: This is not evidence, Your Honor.
4 At most, this is a demonstrative. Even as a demonstrative,
5 we object to it as methodologically unsound as we'll show in
6 our cross examination, but it's certainly not evidence.

7 THE COURT: It certainly -- Mr. Nicholas?

8 MR. NICHOLAS: It's a demonstrative exhibit. It's
9 a demonstrative. It's not -- it's not evidence.

10 THE COURT: Yes. I'm not going to admit it into
11 evidence, Mr. Farrell. So, what are you going to do with
12 the rest of the slides?

13 MR. FARRELL: I guess we'll read them in.

14 THE COURT: Just leave them in?

15 MR. FARRELL: Read them in? Okay.

16 BY MR. FARRELL:

17 Q. Go to D, please.

18 THE COURT: I appreciate your effort to shorten
19 this.

20 THE WITNESS: I do, too, Your Honor.

21 BY MR. FARRELL:

22 Q. Methodology D is three times 12-month average which, as
23 you've explained, is taking a 12-month average, multiplying
24 it by three, to set the cap at threshold. Would you please
25 read into the record and report to the judge what your

1 findings are?

2 **A.** AmerisourceBergen for flagged orders of oxycodone,
3 8,360,740, or 65.3 percent.

4 Flagged orders of hydrocodone, 15,701,930, or 69.4
5 percent dosage units.

6 Cardinal Health, 9,567,580, or 55.7 percent of dosage
7 units.

8 Hydrocodone --

9 THE COURT: I'm sorry. Go ahead.

10 THE WITNESS: That's okay, Your Honor. It's your
11 court.

12 14,957,360, 83.5 percent dosage units.

13 And for McKesson, 1,005,320 dosage units, or
14 25.2 percent of oxycodone.

15 And hydrocodone, 1,245,640, or 33.4 percent of dosage
16 units, Your Honor.

17 BY MR. FARRELL:

18 **Q.** Now, let's go to methodology, E as in Echo. This is
19 the maximum 8,000 dosage units a month. Would you please
20 report to the Court your findings applying this methodology
21 to the data to the three defendants?

22 **A.** For AmerisourceBergen for oxycodone, Your Honor,
23 10,446,280, 81.5 percent dosage units.

24 Hydrocodone, 21,679,760, 95.8 percent.

25 For Cardinal Health, 13,274,080, or 77.2 percent of

1 oxycodone dosage units.

2 For hydrocodone, 16,159,150, or 90.2 percent.

3 Finally, at the bottom, McKesson, for oxycodone
4 2,098,560, 52.7 percent.

5 And for hydrocodone dosage units, 2,484,640, or 66.6
6 percent.

7 **Q.** And, finally, the last methodology, F, the pickers and
8 packers maximum daily dosage units, would you please report
9 to the Court your findings?

10 **A.** AmerisourceBergen for oxycodone dosage units,
11 12,459,020, 97.3 percent.

12 For hydrocodone dosage units, 22,582,020, or
13 99.8 percent of dosage units.

14 Cardinal Health for oxycodone, 16,527,880 dosage units,
15 or 96.2 percent.

16 For hydrocodone, 17,688,100, or 98 percent of dosage
17 units.

18 McKesson for oxycodone dosage units, 3,713,000, or
19 93.2 percent dosage units.

20 And for hydrocodone dosage units, 3,648,650, 97.9
21 percent.

22 **Q.** Very good. Now, Mr. Rafalski, this -- these numbers
23 that you've just read into the record --

24 **A.** Yes, sir.

25 **Q.** -- are in the -- you're using the assumption that there

1 is no due diligence and this is what should have happened
2 when the fire alarm went off, correct?

3 **A.** Assuming no due diligence. What -- I don't --

4 **Q.** So -- so, have we asked you to review all of the due
5 diligence files made available in this litigation?

6 **A.** Yes, sir, you have.

7 **Q.** And have you identified them in your reliance
8 materials?

9 **A.** I have, Your Honor.

10 **Q.** And have you gone through the customer files and the
11 documents produced by AmerisourceBergen, McKesson and
12 Cardinal Health?

13 **A.** I have, Your Honor.

14 **Q.** And have you found sufficient evidence in the record to
15 dispel the suspicion of any of these orders that -- that
16 were or should have been flagged?

17 **A.** I have not, Your Honor.

18 **Q.** Now, let's go to -- did we ask you to review the actual
19 suspicious orders that were reported and disclosed by the
20 defendants in this litigation?

21 **A.** Yes. I'm not sure you asked me to. I mean, that was
22 part of what I did as part of my review of all of the
23 material, but that was one of the primary things that I
24 looked at.

25 **MR. FARRELL:** Can we please bring up at that

1 AmerisourceBergen slide?

2 BY MR. FARRELL:

3 **Q.** Mr. Rafalski, you previously testified that there were
4 77,398 transactions by AmerisourceBergen with pharmacies in
5 Huntington-Cabell County, West Virginia. Based on your
6 review of the files, how many of those transactions were
7 reported by AmerisourceBergen to the DEA as suspicious?

8 **A.** As listed there, Your Honor, by year, I believe that
9 total is 45.

10 **Q.** And will you read into the record each of the years and
11 the numbers?

12 **A.** 2007, 2 pre-shipping reporting; 2008, 4 pre-shipment
13 reporting; 2009, 12 pre-shipment reporting; 2010, 5
14 pre-shipment reporting; 2011, 1 pre-shipment reporting;
15 2012, 4 pre-shipment reporting; and 2013, 11 pre-shipment
16 reporting. And there were -- no reporting post-shipment.

17 **Q.** How about -- I'm told that you missed 2014.

18 **A.** Oh, I'm sorry. Your Honor, 6 for 2014.

19 **Q.** And then, in 2015, '16, '17 and '18, how many were
20 there?

21 **A.** There were 0, Your Honor.

22 **Q.** So, out of the 77,000-plus transactions, what's the
23 total number of orders reported as suspicious?

24 **A.** 45.

25 **Q.** Now, what is it that we're suspicious of? Let's talk

1 to the judge briefly. Why are -- what are we suspicious of
2 happening?

3 **A.** Diversion. Potential for diversion, Your Honor.

4 **Q.** Diversion of what?

5 **A.** Of the controlled substances, that they could leak or
6 be not used properly. It would be an illicit use.

7 **Q.** And so, if you're suspicious, are you suspicious of the
8 orders more likely than not being diverted into the illicit
9 market?

10 **A.** That's correct. If you don't dispel the suspicion of
11 that order and of future orders, if you hadn't removed that
12 suspicion of diversion or dispelled it, more likely than
13 not, that's what would occur, Your Honor, or my belief.

14 **Q.** Let's go to the next slide. This is Cardinal Health.
15 Of the 92,915 transactions, which admittedly go into a
16 longer data time frame than the other defendants, how many
17 suspicious orders were you able to find in the record
18 between 1996 and 2012 -- 2011?

19 **A.** 0.

20 **Q.** Well, that's not true, is it, Mr. Rafalski?

21 **A.** Oh, I think that's changed. I'm sorry. For 2010 would
22 be the first order that was discovered.

23 **Q.** So, between -- in 1996, how many suspicious orders were
24 reported?

25 **A.** 0 up through 19 -- 2009.

1 Q. And then in 2010, how many were reported?

2 A. 1.

3 Q. And how about 2012?

4 A. 2012, 115.

5 Q. I'm sorry. I missed 2011.

6 A. 2011, 0.

7 Q. And then, beginning in 2012, how many suspicious orders
8 were reported?

9 A. 15 for 2012; 86 for 2013; 5 for --

10 THE COURT: Did you say 15 for 2012?

11 THE WITNESS: 115, Your Honor. I'm sorry. Again,
12 86 for 2013; 5 for 2014; 19 for 2015; 34 for 2016; 32 for
13 2017.

14 Q. So, just for purposes of the record, between 1996 and
15 2011, Cardinal Health reported one suspicious order?

16 A. That's correct, Your Honor.

17 Q. Now, let's go to the next slide, please. And, again,
18 this is McKesson and of the 18,862 transactions, how many
19 suspicious orders were reported by McKesson from 1996
20 through 2012?

21 A. That would be 0, Your Honor.

22 Q. And then beginning in 2013, how many suspicious orders
23 were reported?

24 A. Five orders in 2013; 29 orders in 2014; 20 orders in
25 2015; 10 orders in 2016; 2 in 2017; and 13 in 2018, Your

1 Honor.

2 **Q.** Now, with regard to Rite Aid, McKesson's relationship
3 with Rite Aid, did you find any evidence in the record that
4 McKesson conducted sufficient due diligence of the Rite Aid
5 stores in Huntington-Cabell County, West Virginia?

6 **A.** I did not, Your Honor.

7 **Q.** Did you find any evidence that McKesson conducted
8 sufficient due diligence when increasing thresholds of
9 hydrocodone and oxycodone for Rite Aid stores in
10 Huntington-Cabell County, West Virginia?

11 **A.** Your Honor, I did not.

12 **Q.** And did you find any evidence that McKesson was
13 sufficiently monitoring Rite Aid's self-distribution of
14 hydrocodone to its stores in Huntington-Cabell County, West
15 Virginia?

16 MR. SCHMIDT: Objection, Your Honor. Based on an
17 implied legal duty that doesn't exist, we can't monitor
18 someone's independent conduct from us.

19 THE COURT: Well, overruled.

20 Go ahead, Mr. Farrell.

21 THE WITNESS: No, they didn't, Your Honor.

22 BY MR. FARRELL:

23 **Q.** And did you find sufficient evidence of an appropriate
24 Level I or Level II review by McKesson for retail national
25 account customers in Huntington-Cabell County, West

1 Virginia?

2 **A.** I did not, Your Honor.

3 **Q.** Mr. Rafalski, do you have an opinion whether
4 AmerisourceBergen maintained effective control to prevent
5 diversion of prescription opioids into the illicit market in
6 Huntington-Cabell County, West Virginia?

7 **A.** Yes, Your Honor, I do.

8 **Q.** What is that opinion?

9 **A.** Failure to maintain effective controls to prevent
10 diversion of controlled substances.

11 MR. NICHOLAS: Your Honor, I'll object and ask to
12 strike that testimony as a legal conclusion.

13 THE COURT: Well, overruled.

14 BY MR. FARRELL:

15 **Q.** So, let's back up. Do you have an opinion and I'll --
16 I'm going to use the collective to save us some time.

17 THE COURT: Overrule the objection and deny the
18 motion to strike.

19 Go ahead, Mr. Farrell.

20 BY MR. FARRELL:

21 **Q.** Do you have an opinion whether AmerisourceBergen
22 maintained effective control to prevent diversion of
23 prescription opioids into the illicit market in
24 Huntington-Cabell County, West Virginia?

25 **A.** I do.

1 Q. What is that opinion?

2 A. That they did, Your Honor.

3 Q. Do you have an opinion whether Cardinal Health
4 maintained effective control to prevent diversion of
5 prescription opioids into the illicit market in
6 Huntington-Cabell County, West Virginia?

7 MS. MAINIGI: Objection, Your Honor. Calls for a
8 legal conclusion inconsistent with the Geldhof ruling.

9 THE WITNESS: I do, Your Honor.

10 BY MR. FARRELL:

11 Q. What is that opinion?

12 A. That they did.

13 Q. That they did not?

14 A. They did not. I'm sorry. Yes.

15 Q. Do you have an opinion whether McKesson maintained
16 effective control to prevent diversion of prescription
17 opioids into the illicit market in Huntington-Cabell County,
18 West Virginia?

19 MR. SCHMIDT: Same objection, Your Honor.

20 THE COURT: Overruled.

21 THE WITNESS: I do, Your Honor.

22 BY MR. FARRELL:

23 Q. What is that opinion?

24 A. That they did not.

25 Q. Do you have an opinion whether AmerisourceBergen,

1 Cardinal Health and McKesson each individually designed and
2 operated an effective system to identify, block and report
3 suspicious orders arising out of Huntington-Cabell County,
4 West Virginia?

5 **A.** I do, Your Honor.

6 **Q.** And what is that opinion?

7 **A.** That they did not.

8 **Q.** Do you have an opinion whether these failures were
9 systemic?

10 **A.** I do, Your Honor.

11 **Q.** And what is your opinion?

12 **A.** That they were.

13 **Q.** Do you have an opinion --

14 THE COURT: What do you mean by systemic failure?

15 THE WITNESS: Systemic would -- the difference
16 would be when I looked at the due diligence, maybe there was
17 a flaw or a missed one. Systemic would mean that it was
18 widespread, that it was --

19 THE COURT: Okay. Ms. Mainigi?

20 MS. MAINIGI: I object to that, Your Honor. He
21 has absolutely no basis in terms of what he reviewed to do
22 that and ultimately it calls for a legal conclusion but we
23 can cross examine him on it.

24 THE COURT: Overruled.

25 MR. FARRELL: All right. I'm being told that I

1 need to -- because of the objections and the clarity, I need
2 to go back and re-ask the first question on
3 AmerisourceBergen.

4 BY MR. FARRELL:

5 **Q.** You've stated earlier that you do -- let me start all
6 over with that. Do you have an opinion whether
7 AmerisourceBergen maintained effective control to prevent
8 diversion of prescription opioids into the illicit market in
9 Cabell County, West Virginia?

10 **A.** I do, Your Honor.

11 **Q.** And what is your opinion?

12 **A.** They did not.

13 THE COURT: Haven't you already asked him that?

14 MR. FARRELL: I was told that I --

15 THE COURT: Oh, you wanted to rephrase the
16 question?

17 MR. FARRELL: I was told I bollixed it and so I
18 was trying to fix it.

19 THE WITNESS: I might have misunderstood it, Your
20 Honor.

21 THE COURT: Okay. All right. I'm sorry. Go
22 ahead.

23 BY MR. FARRELL:

24 **Q.** Do you have an opinion whether these systemic failures
25 were a substantial factor in the diversion of prescription

1 opioids into the illicit market in Huntington-Cabell County,
2 West Virginia?

3 MS. MAINIGI: Objection, Your Honor. This calls
4 -- clearly calls for a legal conclusion.

5 MR. SCHMIDT: It also calls for an undisclosed
6 causation opinion --

7 MS. MAINIGI: Join.

8 MR. SCHMIDT: -- that he's not qualified to give,
9 he doesn't have a methodology for giving, and he's not
10 disclosed.

11 MR. NICHOLAS: Joined on both objections on behalf
12 of AmerisourceBergen.

13 THE COURT: All right. I'm going to overrule the
14 objections and allow him to continue.

15 THE WITNESS: I do.

16 BY MR. FARRELL:

17 **Q.** And what is that opinion?

18 **A.** Could you repeat the question, please?

19 **Q.** Do you have an opinion whether these systemic failures
20 were a substantial factor in the diversion of prescription
21 opioids into the illicit market in Huntington-Cabell County,
22 West Virginia?

23 **A.** They were, Your Honor.

24 **Q.** I asked you first, do you have an opinion?

25 **A.** I said I do.

1 Q. And what is that opinion?

2 A. That they were.

3 Q. Do you have an opinion whether the orders the
4 defendants knew or should have known were suspicious were
5 likely to be diverted into the illicit market in
6 Huntington-Cabell County, West Virginia?

7 A. I do.

8 MS. MAINIGI: Same objection, Your Honor.

9 THE COURT: Overruled.

10 MR. SCHMIDT: Same objection and to avoid
11 disruption, may we just have a running objection to these
12 lines of questioning?

13 THE COURT: You may.

14 MR. SCHMIDT: Thank you.

15 MR. NICHOLAS: I join in that.

16 THE COURT: Right. Right. The record will show a
17 continuing objection to the entire line of questioning on
18 behalf of all three defendants.

19 You may proceed.

20 MR. SCHMIDT: Thank you, Your Honor.

21 BY MR. FARRELL:

22 Q. So, starting over, do you have an opinion whether the
23 orders the defendants knew or should have known were
24 suspicious were likely to be diverted into the illicit
25 market in Huntington-Cabell County, West Virginia?

1 **A.** I do, Your Honor.

2 **Q.** And what is that opinion?

3 **A.** That they were.

4 **Q.** And do you hold these opinions to a reasonable degree
5 of certainty?

6 **A.** I do, Your Honor.

7 MR. FARRELL: Judge, may I have a moment to
8 confer?

9 THE COURT: Yes.

10 (Pause)

11 MR. FARRELL: Judge, without belaboring the point,
12 can I have five minutes to see? I believe I'm done.

13 THE COURT: Well, I've got to quit early because
14 of a problem that came up with the noon hearing, so I'm
15 going to suggest we pull the plug on this now and come back
16 at 1:30. Is that okay with everybody?

17 MR. FARRELL: Yes, Your Honor.

18 THE COURT: All right.

19 (Recess taken)

20 (Proceedings resumed at 1:30 p.m. as follows:)

21 THE COURT: Mr. Rafalski, you can resume the
22 witness stand. You're still under oath, sir.

23 Do you have anymore questions, Mr. Farrell?

24 MR. FARRELL: A few, Your Honor. May I proceed?

25 THE COURT: Yes.

1 BY MR. FARRELL:

2 Q. Mr. Rafalski, I have a few follow-up questions on
3 the methodology of your methodologies.

4 A. Okay.

5 Q. Did you provide the methodologies to an expert with
6 experience running searches on the ARCOS database?

7 A. I did.

8 Q. Who was that?

9 A. Mr. McCann, Dr. McCann. I'm sorry.

10 Q. Did you ask that Dr. McCann apply those methodologies
11 to the ARCOS database?

12 A. I did, Your Honor.

13 Q. Did Dr. McCann apply the methodologies as you
14 requested?

15 A. He did, Your Honor.

16 Q. And did Dr. McCann make you aware of the results?

17 A. Yes, Your Honor.

18 Q. Did you incorporate and rely upon those results?

19 A. I did, Your Honor.

20 Q. Are you familiar with Dr. McCann's work analyzing the
21 ARCOS database?

22 A. I am.

23 Q. In your experience, do you find his work reliable?

24 A. I do, Your Honor.

25 Q. Do DEA agents and diversion investigators commonly rely

1 on the DEA's computer professionals to run searches on the
2 ARCOS data?

3 **A.** In some circumstances, yes, sir.

4 **Q.** And do experts in your field reasonably rely on the
5 type of calculations Dr. McCann performed for you?

6 **A.** Yes, Your Honor.

7 MR. FARRELL: No further questions.

8 THE COURT: You may cross-examine.

9 MR. SCHMIDT: Thank you, Your Honor.

10 May I proceed, Your Honor?

11 THE COURT: Yes.

12 CROSS EXAMINATION

13 BY MR. SCHMIDT:

14 **Q.** Mr. Rafalski, it's good to see you. We were joking
15 in the hall that we've spent a lot of time together.

16 **A.** We have, Mr. Schmidt.

17 **Q.** I'm going to try to be very straight and direct in my
18 questions, very targeted. I'm going to ask you, if you can,
19 to be just as concise as you were in answering Mr. Farrell's
20 questions as you are in answering mine. Is that fair?

21 **A.** Yeah, I understand that, Your Honor, and I'll do my
22 best to do that.

23 **Q.** Okay. Let me start off by asking you some questions
24 about your methodology and how your opinions fit into the
25 broader case.

1 The plaintiff lawyers in this case only asked you to
2 evaluate the three defendants in this case; correct?

3 **A.** That's correct, Your Honor.

4 **Q.** You did not evaluate any companies the plaintiff
5 lawyers are not suing in this case. True?

6 **A.** I did not, Your Honor, only the three defendants.

7 **Q.** When it came to your work, you only evaluated the three
8 entities the lawyers pointed you to as opposed to evaluating
9 all distributors, all manufacturers, all pharmacies;
10 correct?

11 **A.** Your Honor, that's a correct statement, only the three
12 defendants.

13 **Q.** Let's talk about some of those other groups. Let's
14 start with doctors.

15 You recognize that doctors and other prescribers are
16 responsible for determining medical need when they write
17 prescriptions for opioids?

18 **A.** That's, that's one of the requirements for a physician,
19 Your Honor.

20 **Q.** And they're only supposed to write prescriptions for
21 opioids if they have a doctor/patient relationship and make
22 a judgment that a patient has legitimate medical needs for
23 those opioids. True?

24 **A.** That's a correct statement, Your Honor.

25 **Q.** And, in fact, the DEA regulations state that the

1 responsibility for the proper prescribing and dispensing of
2 controlled substances is upon the prescribing practitioner.
3 You're familiar with that law. Correct?

4 **A.** Yes, sir.

5 **Q.** And that law governed the whole time you were at the
6 DEA; it still governs today. Correct?

7 **A.** The law is the same, Your Honor.

8 **Q.** The DEA does not expect distributors to second-guess
9 the legitimate medical judgments of prescribers. True?

10 **A.** Well, I would agree with that, Your Honor, in general
11 terms unless they were to know some information or observe
12 something way outside of the normal.

13 **Q.** That's why I asked about legitimate medical need. When
14 it comes to legitimate medical judgments, the prescribers,
15 distributors are not supposed to second-guess those. True?

16 **A.** I guess if they -- Your Honor, if they determine
17 they're legitimate, then that's a correct statement.

18 **Q.** There's no determination -- no requirement in the
19 regulations that distributors have to affirmatively
20 determine that prescribing decisions are legitimate, is
21 there?

22 **A.** I'd agree with that.

23 **Q.** Okay. Thank you. The vast majority of doctors, you
24 agree, are trying to do the right thing?

25 **A.** Not that I'm an expert in that area, Your Honor, but

1 that's one of my beliefs. I would hope that all doctors are
2 trying to do the right thing.

3 **Q.** Are DEA policy statements important to you in your
4 work?

5 **A.** I think they're a guide, yes. I'd agree with that
6 statement, Your Honor.

7 **Q.** When you talked to -- when you talk about guidance you
8 looked at, you look to guidance in DEA policy statements?

9 **A.** There would be occasion, yes.

10 MR. SCHMIDT: May I approach, Your Honor?

11 THE COURT: Yes.

12 BY MR. SCHMIDT:

13 **Q.** Sir, I've handed you what I've marked as
14 Defendants' West Virginia 3076. Do you see that at the
15 top it's dated September 6th, 2006?

16 **A.** I see that, Your Honor.

17 **Q.** And do you see that it's written by the Drug
18 Enforcement Administration, your former employer?

19 **A.** That is correct. I do see that, Your Honor.

20 **Q.** And if you look at the second page, do you see where it
21 says "Department of Justice Drug Enforcement Administration
22 Dispensing Controlled Substances for the Treatment of Pain"?
23 Do you see that?

24 **A.** Yes, I do.

25 **Q.** And below that it says "Agency DEA Action Policy

1 Statement." Do you see that? It's immediately below in the
2 upper left corner.

3 **A.** I do see that under "Action," yes, sir.

4 **Q.** This is the kind of DEA policy statement specifically
5 relating to prescription opioids that we were just
6 referencing; correct?

7 **A.** Generally, yes. I think this is a proposal for
8 multiple prescriptions for Schedule II. But I agree that's
9 what the policy statement says.

10 MR. SCHMIDT: We move this into evidence,
11 Defendants' West Virginia 3076.

12 THE COURT: Is there any objection?

13 MR. FARRELL: Yes, Your Honor.

14 THE COURT: What is it?

15 MR. FARRELL: Well, this is hearsay, and unless
16 this Court takes judicial notice of a public document. But
17 in addition to that, there's been no foundation that this
18 witness is familiar with this policy statement from the DEA.

19 MR. SCHMIDT: I don't think the witness -- an
20 expert witness gets to decide the scope of his cross
21 examination by a limited review of documents. There is
22 foundation that this is the type of document he would look
23 at.

24 THE COURT: This comes in under the public records
25 exception to the hearsay rule, does it not?

1 MR. SCHMIDT: Yes.

2 THE COURT: Objection is overruled. I'll admit
3 it.

4 BY MR. SCHMIDT:

5 Q. Okay. Let's put it up on the screen, please. And
6 we don't need to go back through the background
7 information.

8 What I want to do is go to Page 5 of the document
9 looking at the numbers in the lower left-hand corner,
10 please. And tell me when you're there. And we also have it
11 up on the screen. It's just to your right. Do you see
12 that?

13 A. Yes. One second.

14 Q. And, specifically, if we cull out the right column,
15 there's a heading that says, "The number of physicians who
16 prescribe controlled substances in violation of the CSA is
17 extremely small and there is no DEA crack-down on
18 physicians."

19 Do you see that?

20 A. I see what that says, yes.

21 Q. And then it says in 2006 in the Federal Register in
22 this official DEA policy statement, DEA recognizes that the
23 overwhelming majority of American physicians who prescribe
24 controlled substances do so for legitimate medical purposes.

25 Do you disagree with that statement?

1 **A.** I do not.

2 **Q.** You agree with that?

3 **A.** Yes, Your Honor, I agree with that.

4 **Q.** In fact, the overwhelming majority of physicians who
5 prescribe controlled substances do so in a legitimate manner
6 that will never warrant scrutiny by federal or state law
7 enforcement officials.

8 Do you agree with that?

9 **A.** Your Honor, I do agree with that statement, too.

10 **Q.** Do you recall when you were at the DEA that the head of
11 the Office of Diversion Control was Joseph Rannazzisi?

12 **A.** I do, sir.

13 **Q.** And you're aware that he has publicly stated under oath
14 in testimony that 99 point -- 99 percent of doctors
15 prescribe opioids for legitimate medical purposes? You and
16 I have looked at that testimony together. Correct?

17 **A.** Your Honor, we have and I do recall that testimony.

18 **Q.** And you agree with that testimony; correct?

19 **A.** Yes.

20 **Q.** You're aware that the former head of the DEA, Robert
21 Patterson, has similarly testified under oath to our United
22 States Congress that 99.99 percent of doctors are trying to
23 do right by their patients?

24 **A.** I do not recall that testimony, hearing that testimony
25 before, Your Honor.

1 Q. I've shown you that testimony. Do you recall that?

2 A. I do not. 99.99? I do not.

3 Q. Well, do you agree -- let me ask it this way. Do you
4 agree with the statement made by Mr. Patterson of the DEA,
5 formerly of the DEA testifying in front of Congress that
6 99.99 percent of doctors are trying to do the right thing?

7 Do you agree or disagree with that statement?

8 A. It's a difficult decision, Your Honor, because I'm
9 thinking about the approximately one million physicians in
10 the United States and calculating what one tenth of
11 one percent would be. I guess generally I don't have any
12 information to disagree with it.

13 Q. Okay.

14 A. I'm not, I'm not as certain when you bring it down to
15 one tenth of one percent.

16 Q. Okay. No reason to disagree with it?

17 A. No, I don't have any information to disagree other than
18 my experience in working with the DEA might taint my opinion
19 a little bit because I -- you know, prior to that, I didn't
20 have the same contact with physicians that were having
21 problems with dispensing and all other issues. But other
22 than that, I do not, Mr. Schmidt.

23 Q. You agree that the medical community bears some
24 responsibility for the opioid crisis; correct?

25 A. Your Honor, I believe that probably everybody bears

1 some responsibility for the opioid crisis. I, I don't think
2 that anyone can sit here today that took a role in trying to
3 combat it would ever say they did everything perfectly.

4 **Q.** Does that include the DEA?

5 **A.** That includes the DEA.

6 **Q.** Does that include Joe Rannazzisi, former head of the
7 Office of Diversion Control of the DEA?

8 **A.** I guess Mr. Rannazzisi would speak for himself.

9 **Q.** I'm asking your view, sir.

10 **A.** I, I've already stated I think everybody, if they were
11 able to look back and look at what they did, I don't think
12 there's anybody in America that could say, "I did everything
13 perfect."

14 **Q.** Does that include Mr. Rannazzisi in your view?

15 **A.** If I make a statement like that, I guess I would hope
16 that he could look back and feel the same way.

17 **Q.** Now, I'll come back to my question and ask you about
18 doctors. Do doctors -- do you agree that doctors bear some
19 responsibility for the opioid crisis?

20 **A.** I believe they do.

21 **Q.** You're testifying here as a DEA expert; correct?

22 **A.** I don't know if I'm a DEA expert. I'm not employed
23 anymore. I'm an expert, I guess, with a DEA background.

24 **Q.** Okay. I don't want to split hairs. You've come here
25 as an expert on DEA topics as a former employee of the DEA;

1 correct?

2 **A.** Yes. I just didn't want to be a DEA expert.

3 **Q.** Are you aware of the DEA's 360 programs?

4 **A.** Not in great detail. It was something that was
5 starting right around my retirement. I think it wasn't
6 really fully rolled out until after I left in 2017.

7 **Q.** Okay. Have you had occasion to look at the DEA's 360
8 program covering Cabell County in connection with your work
9 in this case?

10 **A.** I have not, Your Honor.

11 **Q.** Do you know what causes the DEA has identified through
12 their 360 project as causes of the opioid crisis in Cabell
13 County?

14 **A.** No, I do not.

15 **Q.** That's not something you've looked at in your work?

16 **A.** I believe that I may have looked at a document or some
17 information regarding that. I don't have a direct
18 recollection and I don't want to guess on that topic, Your
19 Honor.

20 MR. SCHMIDT: May I approach, Your Honor?

21 BY MR. SCHMIDT:

22 **Q.** I've handed you a document marked Defendants' West
23 Virginia 2628. Do you see on the cover it says "DEA 360
24 Strategy"?

25 **A.** I see that, Your Honor.

1 Q. And if you look at Page 7 of the document --

2 A. Okay.

3 Q. -- do you see that it covers Cabell, among other
4 counties?

5 A. I see that, sir.

6 Q. It was launched in February, 2017. Do you see that?

7 A. I do.

8 Q. And it covers Cabell County; correct?

9 A. That's a correct statement, sir.

10 Q. Do you see on Page 9 that they have a chart with
11 factors contributing to the opioid problem in West Virginia?

12 A. I see that page, yeah, Your Honor.

13 Q. And do you see under that the third factor is
14 over-prescribing of opioids? Do you see that?

15 A. I agree that that is what that statement says.

16 Q. Do you agree that's a factor contributing to the opioid
17 problem in West Virginia, doctors over-prescribing opioids?

18 A. I think that's a logical statement that there would be
19 some over-prescribing or prescribing issues that would lead
20 to that issue.

21 Q. Do you see they have data and they cite someone named
22 Dr. Gupta who this Court has heard from already?

23 MR. FARRELL: Can you give me a page number?

24 MR. SCHMIDT: Oh, yes, of course. I might have
25 read the wrong one, Page 9. It's 4 on the document. But if

1 you look at the lower numbers, those are the numbers I'm
2 going to be using all through the document.

3 BY MR. SCHMIDT:

4 **Q.** Do you take any issue with the data cited here
5 regarding prescribers over-prescribing opioids in West
6 Virginia coming from the DEA and from Dr. Gupta?

7 **A.** Your Honor, I don't have any problems with the data. I
8 don't have any independent knowledge, or I haven't done any
9 research or looked up, you know, to be able to give an
10 informed comment on that. I don't have any reason to not
11 believe the data, sir.

12 **Q.** Do you see that there's discussion in this DEA 360
13 publication citing Dr. Gupta, citing the DEA, citing the
14 National Institute on Drug Abuse talking about factors
15 contributing to the opioid problem in West Virginia? There
16 is no mention of distributors?

17 **A.** There is not, Your Honor, at least on the two pages
18 we've reviewed so far.

19 MR. SCHMIDT: We'll move this into evidence, Your
20 Honor, Defendants' West Virginia 2628.

21 MR. FARRELL: Objection; hearsay, foundation, and
22 geographic scope.

23 THE COURT: How does it come in, Mr. Schmidt?

24 MR. SCHMIDT: I think it's an official record, and
25 it's certainly a record of the type experts use and would

1 rely on under 703.

2 THE COURT: Well, they can consider it under 703.
3 That doesn't necessarily make it admissible under 703. Is
4 there an exception to the hearsay rule?

5 MR. SCHMIDT: I think it's a government
6 publication.

7 BY MR. SCHMIDT:

8 **Q.** Is this a document you reviewed before, Mr.
9 Rafalski?

10 **A.** I've never seen this before, sir.

11 **Q.** Okay.

12 MR. SCHMIDT: I won't move it in, then, Your
13 Honor.

14 THE COURT: All right.

15 BY MR. SCHMIDT:

16 **Q.** In terms of Cabell County and Huntington, you don't
17 know how many doctors in Cabell/Huntington -- Cabell
18 County and Huntington who wrote prescriptions for
19 opioids during the time period you were looking at in
20 this case; correct?

21 **A.** Your Honor, I did not research that topic, so I do not
22 know.

23 **Q.** So it follows that you conducted no analysis of how
24 many doctors were prescribing legitimately in
25 Huntington/Cabell versus illegitimately. True?

1 **A.** I did not conduct any research on that and I did not
2 look into that matter. So I do not have an opinion on it.

3 **Q.** I'm trying to get you off today, so I'm going to ask
4 you if you can answer just my question. I'm just going to
5 try to ask "yes/no" questions where I can.

6 **A.** Okay. Your Honor, when I can answer "yes/no" I will.

7 THE COURT: Okay. And you can explain your answer
8 when you desire to do so.

9 THE WITNESS: I understand, Your Honor.

10 BY MR. SCHMIDT:

11 **Q.** Your report and your testimony doesn't identify a
12 single doctor who you have identified in Cabell County
13 or Huntington who was prescribing improperly or engaging
14 in diversion. True?

15 **A.** That's correct.

16 **Q.** You talked about Dr. Ognen, a pill mill doctor you
17 investigated in -- was it Michigan?

18 **A.** Toledo, Ohio, sir.

19 **Q.** In Toledo, Ohio, during your work at the DEA. Do you
20 recall that?

21 **A.** I do.

22 **Q.** You didn't conduct that type of investigation of any
23 doctors in Huntington or Cabell as part of your work in this
24 case; correct?

25 **A.** I was not requested to do that type of analysis, Your

1 Honor.

2 **Q.** So did you do it?

3 **A.** I did not.

4 **Q.** Okay. You've not done any kind of analysis of the
5 medical needs for prescription opioids in Cabell County or
6 Huntington relative to the national average; correct?

7 **A.** That's a correct statement. I did not do that.

8 **Q.** So it follows that you can't identify a single instance
9 where an order from McKesson or ABDC or Cardinal went to
10 fill a prescription written by a doctor in Cabell County or
11 Huntington where the doctor was prescribing improperly or
12 engaging in diversion. True?

13 **A.** I don't think that's a true statement.

14 **Q.** Which doctors had prescriptions filled by one of these
15 defendants that was acting improperly or engaging in
16 diversion?

17 **A.** Well, I'm aware of an incident through reviewing of
18 records, doing some research on some of the records for some
19 of the pharmacies that there was a, a pharmacy located in
20 Huntington that was filling prescriptions for the whole pain
21 clinic.

22 **Q.** Okay.

23 **A.** And all 12 of the people involved with the whole pain
24 clinic were all indicted.

25 During the time frame that those doctors were

1 prescribing, they were filling prescriptions. There was a
2 pharmacy or pharmacies in this area filling prescriptions
3 for them.

4 Now, I don't have any independent knowledge to say
5 those specific prescriptions. But based on the totality of
6 all the circumstances, I would say it's likely that there
7 were prescriptions issued that were illicit during that time
8 period.

9 **Q.** Do you know of any pills shipped by McKesson, ABDC, or
10 Cardinal that specifically went to a pill mill doctor or an
11 improper prescription?

12 **A.** As I just testified, I think in this case it's likely.
13 I think the pharmacy I recall being was a customer of
14 McKesson.

15 **Q.** Do you know if that happened?

16 **A.** The distribution?

17 **Q.** Yes, the distribution of pills -- you just mentioned
18 McKesson -- by McKesson that went to fill a prescription
19 that was written by a pill mill doctor?

20 **A.** I don't know that they filled that specific
21 prescription. I just know they went to the pharmacy.

22 **Q.** What was that McKesson customer?

23 **A.** I'm drawing a blank on it.

24 **Q.** It's no one you mentioned in your report; correct?

25 **A.** It's not in my report, no, sir.

1 Q. It's no one you mentioned in your testimony; correct?

2 A. Not so far, that's correct.

3 Q. And you realize we're done with your affirmative
4 testimony from Mr. Farrell; correct?

5 A. I am.

6 Q. Okay. In a similar vein, are you aware of any pills
7 that were shipped by McKesson, ABDC, or Cardinal that ended
8 up filling a prescription that was dispensed other than in
9 response to a licensed prescriber writing a prescription?

10 A. No, I'm not, Your Honor.

11 Q. Let's talk about pharmacies. Pharmacies dispense
12 prescription opioids in response to prescriptions; correct?

13 A. That's correct, sir.

14 Q. And the DEA registers the pharmacies, and the West
15 Virginia Board of Pharmacy licenses the pharmacies in West
16 Virginia; correct?

17 A. That's correct.

18 Q. And both of those, that registration, that licensing
19 are both important; correct?

20 A. Yes. It's required by law.

21 Q. You're not aware of Cardinal, ABDC, or McKesson ever
22 supplying a pharmacy that was not licensed by the DEA?

23 A. I do not, Your Honor.

24 Q. You understand that under DEA rules when you were at
25 the DEA and to this day that pharmacies have a corresponding

1 responsibility to that of the doctor when it comes to
2 prescriptions?

3 **A.** Yes, but, more specifically, the pharmacist.

4 **Q.** The pharmacist?

5 **A.** Not the pharmacy.

6 **Q.** What is that corresponding responsibility that a
7 pharmacist has?

8 **A.** They're supposed to ensure that that prescription was
9 issued for a legitimate medical need and, if necessary, that
10 there was a proper doctor/patient relationship.

11 If while filling the prescription they identify any
12 anomalies or red flags, they have an obligation to resolve
13 those before issuing the prescription.

14 **Q.** And that language, that corresponding responsibility is
15 written into the regulation; correct?

16 **A.** It is a regulation, sir.

17 **Q.** There's no reference to a corresponding responsibility
18 of distributors, correct, in the regulation?

19 **A.** There is not.

20 **Q.** So is it accurate to say that pharmacies have
21 meaningful responsibilities when it comes to prescription
22 opioids?

23 **A.** Yes, but, more specifically, pharmacists.

24 **Q.** Are you aware of any prescription in this case relating
25 to the defendants that was dispensed without a pharmacist

1 present with that pharmacist having that corresponding
2 responsibility?

3 **A.** I am not, Your Honor. That was not part of what I did
4 research for for my report.

5 **Q.** And it's because of that corresponding responsibility
6 that pharmacists have that at the DEA they're often referred
7 to as the last line of defense against diversion; correct?

8 **A.** I've never heard that specific term about pharmacists
9 but --

10 **Q.** Okay.

11 **A.** -- I don't dispute that that could be a term used.

12 **Q.** You never heard that in your work at DEA?

13 **A.** No, I did not.

14 **Q.** Okay.

15 **A.** I, I heard that used for other entities in the closed
16 system, but not for pharmacists.

17 **Q.** A pharmacy can't dispense a prescription opioid without
18 having a prescription from a licensed healthcare prescriber
19 and properly evaluating it. True?

20 **A.** Could you say the end again? I'm sorry.

21 **Q.** Sure. A pharmacy can't dispense prescription opioids
22 without having a prescription in hand from a licensed
23 healthcare professional and properly evaluating it.

24 Correct?

25 **A.** Generally speaking. There's some emergency provisions,

1 Your Honor, where the prescription can follow-up within a
2 certain time frame. So that's part of having it in hand.
3 But, basically, that's a true statement, Your Honor.

4 **Q.** All right. And that statement is true no matter how
5 many prescription opioids are distributed; correct?

6 **A.** That's correct.

7 **Q.** The number of pills that a pharmacy dispenses are
8 directed by the number of prescriptions written by
9 healthcare professionals. True?

10 **A.** Generally speaking, yes.

11 **Q.** You don't know how many pharmacies dispensed
12 prescription opioids during the time period you were looking
13 at in Cabell County and Huntington; correct?

14 **A.** I don't know them off of my -- off the top of my head,
15 but I do have a chart where I have for the three defendants
16 the number of pharmacies. The totality of all the
17 pharmacies, if there were ones that were receiving
18 controlled substances outside of the three defendants, I
19 would not have those. So --

20 **Q.** You weren't -- you weren't tasked with evaluating the
21 pharmacies in Cabell County and Huntington in terms of
22 whether they were complying with their legal obligations;
23 correct?

24 **A.** That's correct, Your Honor. I wasn't evaluating
25 pharmacies.

1 **Q.** You weren't asked to review specific pharmacy records,
2 how the records were maintained, whether they were
3 dispensed, whether their corresponding responsibility was
4 fulfilled by the pharmacists; correct?

5 **A.** That's a correct statement, Mr. Schmidt.

6 **Q.** So you did not undertake those reviews; correct?

7 **A.** I did not, Your Honor.

8 **Q.** Correspondingly, you do not know of any pharmacies in
9 Cabell County or Huntington -- let me actually ask you a
10 different question. You're not offering any opinions about
11 whether diversion occurred at a pharmacy level; correct?

12 **A.** I haven't put that opinion in my report, so I guess
13 that's a true statement, Your Honor.

14 **Q.** You understand that some of the large pharmacy chains
15 act as distributors themselves by self-distributing to
16 themselves; correct?

17 **A.** There's -- it's a possibility for a pharmacy, but
18 there's a rule, a percent rule of how much they can do that.

19 **Q.** With respect, I didn't ask you -- I just asked you if
20 it's correct. Is it correct that some chain pharmacies
21 self-distribute?

22 **A.** General knowledge, I know that. As far as within
23 Cabell County and Huntington, I don't have any knowledge of
24 that occurring.

25 **Q.** Do you know of any pharmacy, chain pharmacy in

1 Huntington or Cabell County that self-distributes?

2 **A.** No, I do not.

3 **Q.** Okay. Some of the pharmacies that are large chains are
4 pharmacies like CVS, Walgreens, Rite-Aid; correct?

5 **A.** Yes.

6 **Q.** And you know they self-distribute in other locations;
7 correct?

8 **A.** I know I've seen things where they might transfer
9 controlled substances back and forth to each other, which is
10 permissible.

11 **Q.** This is now, by my count, the fifth case where you're
12 giving opinions against various defendants, is that correct,
13 regarding prescription opioids?

14 **A.** Yes.

15 **Q.** In other cases you've given the opinions that those
16 chain pharmacies I mentioned have caused the opioid crisis;
17 correct?

18 **A.** Yes.

19 **Q.** In fact, you're going to leave this court and go to
20 give a deposition in another case where you're giving the
21 opinion that those chain pharmacies in another jurisdiction
22 have caused the opioid crisis; correct?

23 **A.** That's correct.

24 **Q.** You know that they had stores in Huntington/Cabell;
25 correct?

1 **A.** They do.

2 **Q.** Did you listen to Dr. McCann when he testified in
3 court?

4 **A.** I did.

5 **Q.** Did you hear him acknowledge that if you remove
6 McKesson's GA shipments, its share of distribution to
7 Huntington/Cabell is lower -- it's number 6 -- lower than
8 several of those chain pharmacies?

9 **A.** I, I don't recall specifically that testimony. I know
10 you and I have discussed that before also. I don't disagree
11 with that statement.

12 **Q.** Okay. Thank you. And you don't know if those
13 pharmacies that you're going next week or the week after to
14 testify about in another case but have not given opinions
15 about here helped cause the opioid crisis in
16 Huntington/Cabell; correct?

17 **A.** Would you say that again, please?

18 **Q.** Sure. You don't know if those pharmacies we were just
19 talking about, those pharmacy chains, if they helped cause
20 the opioid crisis in Huntington/Cabell, do you?

21 **A.** I do not, Your Honor.

22 **Q.** Let's talk about manufacturers. They actually make the
23 prescription opioids; correct?

24 **A.** That is correct.

25 **Q.** They're the ones charged with studying prescription

1 opioids. True?

2 **A.** Some of them, yes.

3 **Q.** Before and after approval; correct?

4 **A.** Yes, some of them, yes.

5 **Q.** They're the ones that get FDA approval for them;
6 correct.

7 **A.** That's correct.

8 **Q.** And you're aware that manufacturers market prescription
9 opioids in various ways to doctors; correct?

10 **A.** I'm aware of that, Your Honor.

11 **Q.** In fact, I want to show you a document that you relied
12 on in that proposition. This is a December, 2003, General
13 Accounting Office Report, Prescription Drugs, Oxycontin
14 Abuse and Diversion and Efforts to Address the Problem.

15 This is one of the documents you relied on in forming
16 your opinions; correct?

17 **A.** I believe it's on my reliance list, yes, sir.

18 MR. SCHMIDT: We move this into evidence, Your
19 Honor, MC-WV-1764.

20 THE COURT: Any objection?

21 MR. FARRELL: None.

22 THE COURT: It's admitted.

23 BY MR. SCHMIDT:

24 **Q.** Let's put that up on the screen, please. Do you
25 see there the cover page I just read from? Do you see

1 that?

2 **A.** Yes, sir.

3 **Q.** I'd like to ask you, if I could, to go to Page 2 of the
4 PDF, please.

5 MR. SCHMIDT: And, again, just for reference for
6 the Court and the witness, it will be the little number in
7 the lower left-hand corner. That will always be the number
8 I'll refer to.

9 THE WITNESS: I've got it, sir.

10 BY MR. SCHMIDT:

11 **Q.** Do you see it says why GAO did this study on the
12 left-hand column?

13 **A.** Yes, top of the left-hand column.

14 **Q.** Yes. And at the bottom it talks about GAO reviewing
15 three things. Do you see that?

16 Why don't you highlight it.

17 **A.** I see it, sir, bottom of that same paragraph.

18 **Q.** I want to focus on the second thing: What factors
19 contributed to the abuse and diversion of Oxycontin. Do you
20 see that?

21 **A.** Yes.

22 **Q.** Is that your understanding that that was one of the
23 purposes of this report to evaluate, in the words of the
24 GAO, what factors contributed to the abuse and diversion of
25 Oxycontin?

1 **A.** I see that. I don't disagree with it.

2 **Q.** Do you agree with it?

3 **A.** I said I do not disagree with it. I agree.

4 **Q.** I asked it the other way.

5 **A.** I understand, same answer.

6 **Q.** Okay. Let's look at Page 8 again in the lower
7 left-hand corner.

8 And do you see that the GAO says -- I'm looking at the
9 bottom full paragraph. They say, "To identify how Purdue
10 marketed and promoted Oxycontin, we interviewed Purdue
11 officials and analyzed company documents and data."

12 And then it says they also reviewed Purdue sales
13 representatives. Do you see that?

14 **A.** I do.

15 **Q.** So when you cited this report, did you have the
16 understanding that the GAO not only interviewed Purdue
17 officials and sales reps, but they went into their documents
18 and their data?

19 **A.** That's what the document says.

20 **Q.** You don't take issue with that; right?

21 **A.** I do not.

22 **Q.** Let's go to the next page, please. And if we look in
23 the top paragraph, toward the bottom of that top
24 paragraph --

25 Will you cull out that top paragraph, please?

1 They say, "We also interviewed --" I'm sorry. They
2 say, "We interviewed FDA officials and examined FDA
3 information regarding the drug's approval and marketing and
4 promotion."

5 Do you see that?

6 **A.** I see that, sir.

7 **Q.** "We also interviewed DEA officials and examined how DEA
8 determined the prevalence of Oxycontin abuse and diversion
9 nationally."

10 Do you see that?

11 **A.** I see that, Your Honor.

12 **Q.** And do you understand that to be an accurate statement
13 of what was done in this report?

14 **A.** That's what the report says.

15 **Q.** You don't take any issue with that?

16 **A.** No. I don't know either way. I don't take issue with
17 it, no, sir.

18 **Q.** Let's look at the next paragraph, please, below
19 "Results." They say "Results in Brief."

20 First sentence: "Purdue conducted an extensive
21 marketing campaign --" I'm sorry. Let me start again.

22 "Purdue conducted an extensive campaign to market and
23 promote Oxycontin using an expanded sales force and multiple
24 promotional approaches to encourage physicians, including
25 primary care specialists, to prescribe Oxycontin as an

1 initial opioid treatment for cancer [sic] pain."

2 Do you recognize the truth of that matter as a factual
3 matter?

4 **A.** Yeah. Even outside of this publication --

5 **Q.** Yes.

6 **A.** -- I recognize that statement.

7 **Q.** Further down do you see that reference to DEA? We've
8 got it highlighted on the screen.

9 **A.** Oh, yeah.

10 **Q.** "DEA has expressed concerns that Purdue's aggressive
11 marketing of Oxycontin focused on promoting the drugs to
12 treat a wide range of conditions to physicians who may not
13 have been adequately trained in pain management."

14 Do you see that?

15 **A.** I do see that.

16 **Q.** And do you take any issue with that finding?

17 **A.** I do not, Your Honor.

18 **Q.** Okay. Now, let's go to Page 18, please.

19 **A.** I'm sorry?

20 **Q.** Page 18, please.

21 **A.** 18?

22 **Q.** Yes, sir. Again, in the bottom lower left corner.

23 Just very quickly, do you see that there is a
24 discussion of the DEA's regulation of controlled substances?

25 **A.** I do.

1 **Q.** And it discusses in the sentence, "DEA has the
2 authority to regulate transactions involving the sale and
3 distribution of controlled substances at the manufacturer
4 and wholesale distributor levels."

5 And then it goes on to talk about registrations. Do
6 you see that?

7 **A.** I do.

8 **Q.** You understand that this report talks -- let's go back
9 to that second page, please, and that language I culled out
10 to you; what factors contributed to the abuse and diversion
11 of Oxycontin. Do you see that?

12 **A.** Yes.

13 **Q.** You understand that this report talks about Purdue as a
14 factor that contributed to the abuse and diversion of
15 Oxycontin?

16 **A.** I believe that's a true statement, sir.

17 **Q.** There's no discussion in here, despite those DEA
18 interviews you talked about, about distributors as a factor
19 that contributed to the abuse and diversion of Oxycontin.
20 True?

21 **A.** It's a lengthy document and I don't have a full
22 recollection of it. I, I don't know that there's any
23 mention of distributors in there.

24 **Q.** Okay.

25 **A.** I don't think I'm going to have time to read it here

1 today.

2 **Q.** I'm not going to ask you to do that. I'll stand on
3 your recollection which I believe to be accurate.

4 Now, manufacturers can't sell prescription opioids or
5 make them unless they're licensed by both the DEA and the
6 state; is that correct?

7 **A.** That's a correct statement, yes, sir.

8 **Q.** And they can only make as many prescription opioids as
9 allowed by the DEA for its annual quota; correct?

10 **A.** That's a correct statement, Your Honor.

11 **Q.** You've offered opinions in some of your other cases
12 that at least some other manufacturers helped cause the
13 opioid crisis; correct?

14 **A.** That's a correct statement, Your Honor.

15 **Q.** And every one of those other manufacturers made
16 prescription opioids that were sold and used in Cabell
17 County and Huntington; correct?

18 **A.** I don't know the accuracy of that statement.

19 **Q.** Okay. Can you carve any out that weren't --

20 **A.** No, I cannot but I, I don't have any definitive
21 knowledge of any that did. I think it's a logical statement
22 that manufacturers sent manufactured products into the
23 county. But to name them specifically, I can't do that.

24 **Q.** You're not offering opinions against any manufacturers
25 here; correct?

1 **A.** I am not and I was not asked to.

2 **Q.** And that's why you're not offering opinions because the
3 lawyers didn't ask you; correct?

4 MR. FARRELL: Objection, Your Honor,
5 argumentative.

6 THE COURT: What's the basis of the objection?

7 MR. FARRELL: It's argumentative referencing
8 plaintiffs' lawyers.

9 THE COURT: Overruled.

10 You can answer if you can.

11 THE WITNESS: I can. I was not asked to review
12 and to provide a report in regard to the manufacturers, Your
13 Honor.

14 BY MR. SCHMIDT:

15 **Q.** And that's why you did not; correct?

16 **A.** Yes. I only did what I was asked to do. I didn't go
17 outside of the scope of that.

18 **Q.** And that's true even though in other jurisdictions you
19 have identified specific manufacturers as engaging in worse
20 conduct than you allege against any manufacturer here;
21 correct?

22 **A.** I only provided opinions on those companies or drug
23 companies or manufacturers or distributors that I was asked
24 to. That's a correct statement, yes.

25 **Q.** I was asking you something different, sir. Let me try

1 it a little differently.

2 You recognize that the companies, the manufacturers
3 you've testified about in other cases, you have alleged even
4 worse conduct against them than you have alleged against the
5 defendants here; correct?

6 **A.** I don't think it's worse. I think it's the same on
7 maintenance of effective controls to prevent diversion.

8 **Q.** Every defendant here has had a SOMS for years and years
9 and years; correct? A Suspicious Order Monitoring Program;
10 correct?

11 **A.** Yes.

12 **Q.** And you've alleged at least one manufacturer never had
13 one all the way up until 2018; correct?

14 **A.** I don't directly recall that in one of my reports. I'm
15 not saying it doesn't appear, but I don't have any direct
16 recollection right now of that, Your Honor.

17 **Q.** You said that about a company called Insys, didn't you,
18 that they never had a SOMS all the way through 2018?

19 **A.** I don't think I've provided an opinion on Insys.

20 **Q.** Let's just cull it up on the screen. Can we cull up
21 tab 14, Mr. Rafalski's MDL expert report? Page 187, please.

22 MR. FARRELL: Judge, I'm going to object. I think
23 this is, first of all, improper impeachment if that's what
24 it is; or if he's going to refresh the witness's
25 recollection, then he should do so by presenting it first.

1 More importantly, this is outside the scope of the
2 purpose and role of Mr. Rafalski in this case. As the Court
3 is aware, and the defendants are certainly aware, the reason
4 this case got remanded was because of a stipulation severing
5 the other defendants.

6 So to characterize Mr. Rafalski's testimony in the way
7 that Mr. Schmidt is doing so is contrary to the record, is
8 unfair to the witness, and is argumentative.

9 MR. SCHMIDT: I think it's a fundamental
10 methodological question of why he's focusing on these
11 defendants and the role of other defendants. I don't
12 understand how he could give a single opinion as he did at
13 the end when he gave a series of *ipsa dixit* opinions.

14 THE COURT: I agree. I think that this is proper
15 cross-examination. He's issued other reports. You're
16 entitled to inquire about his conclusions in his reports and
17 see if they're consistent with what he said here. I'll let
18 you do it.

19 MR. SCHMIDT: Thank you, Your Honor.

20 Could we go to Page 187, please?

21 BY MR. SCHMIDT:

22 **Q.** Do you see your signature right there?

23 **A.** I do.

24 **Q.** Do you recognize that as your signature?

25 **A.** That is my signature.

1 Q. Dated April 15th, 2019?

2 A. Yes, sir.

3 Q. And do you see item 4 right above your signature,
4 "Deposition testimony by current Insys employees has
5 confirmed that Insys failed to implement any SOMS system or
6 maintain any SOMS protocols until 2018."

7 Do you see that?

8 A. I see that, Your Honor.

9 Q. Were you being truthful when you provided that report,
10 sir?

11 A. I was. I just didn't recall it, sir.

12 Q. Let me ask you now about distributors. Distributors
13 ship medications from the manufacturers that make them to
14 pharmacies and other entities that dispense them; correct?

15 A. Yes, any registrant that has the ability to purchase
16 them, yes, sir.

17 Q. In doing that, distributors play an important role in
18 ensuring an adequate and uninterrupted supply of legitimate
19 prescription opioids; correct?

20 A. I believe that's the role -- one of the roles of a
21 distributor, yes, sir.

22 Q. They don't fill prescriptions brought to them. That's
23 the role of the pharmacy. Correct?

24 A. That's correct, Your Honor.

25 Q. They don't check the prescriptions that patients bring

1 into a pharmacy; correct?

2 **A.** That's a correct statement.

3 **Q.** In fact, they don't have access to individual patient
4 prescriptions or individual patient data; correct?

5 **A.** That's a correct statement.

6 **Q.** Privacy laws actually prevent that; correct?

7 **A.** HIPAA requirements would prohibit that, sir.

8 **Q.** Those are privacy laws; right?

9 **A.** Yes, they are.

10 **Q.** So distributors don't have the information to evaluate
11 the medical need of an individual patient presenting an
12 individual prescription; correct?

13 **A.** That's a correct statement, Your Honor, they do not.

14 **Q.** You're not aware of any instance where one of the three
15 distributors in this case directly interacted with a doctor
16 or a patient in Huntington or Cabell County, are you?

17 **A.** I'm not aware if that occurred, sir.

18 **Q.** Let me ask you a question about the relationship
19 between pharmacies and distributors. You're aware that when
20 a distributor cuts off a customer, it's common that that
21 pharmacy will go find another distributor to supply its
22 pills; right?

23 **A.** That's true, yes, sir.

24 **Q.** In fact, in your work experience you're aware of no
25 instance ever when a pharmacy has cut off -- I'm sorry -- a

1 distributor has cut off a pharmacy and that pharmacy has
2 gone out of business because they can't find another
3 distributor; correct?

4 **A.** No, I'm not, not immediately.

5 **Q.** What does cut off a pharmacy is if the DEA pulls the
6 pharmacist's registration -- or I'm sorry -- the pharmacy's
7 registration; correct?

8 **A.** Yes. If the DEA or the state was to remove the
9 licensure from the pharmacy, they would stop immediately.

10 **Q.** You agree that there are hundreds of distributors in
11 the United States?

12 **A.** Yes.

13 **Q.** And you agree from reviewing Dr. McCann's data that
14 dozens of distributors supply pharmacies in Huntington and
15 Cabell?

16 **A.** Dozens? I think that may be a little high, but I
17 don't, I don't have any direct recollection to dispute that.

18 **Q.** Dr. McCann testified it was 36. Is that accurate?

19 **A.** If he testified, then that's accurate.

20 **Q.** Okay. And that's two and a half dozen; right?

21 **A.** Yes.

22 **Q.** You conducted no analysis of the distributors that
23 shipped into Huntington and Cabell County other than
24 McKesson, Cardinal, and ABDC; correct?

25 **A.** That's correct, Your Honor. Those are the only three I

1 reviewed.

2 **Q.** To take one example of the distributors you failed to
3 address, the distributor Miami-Luken had a high level of
4 conduct in West Virginia; correct?

5 **A.** I'm aware that they were distributing also into the
6 county and the city at considerable amounts, Your Honor.

7 **Q.** Do they still exist?

8 **A.** I believe they do. I think they have some legal
9 matters pending, but I think they still have their
10 registration.

11 **Q.** What are those legal matters pending?

12 **A.** I believe there are some criminal charges pending
13 against the company.

14 **Q.** And you did no analysis of Miami-Luken's efforts to
15 prevent diversion and comply with the CSA; correct?

16 **A.** I was not asked to do that. No, Your Honor, I did not.

17 **Q.** Did you look at a pharmacy called A-Plus Pharmacy in
18 your work?

19 **A.** In Cabell and Huntington?

20 **Q.** Yes. It was a Miami-Luken pharmacy.

21 **A.** I believe so.

22 **Q.** Do you know that -- then you know that ABDC, Cardinal,
23 and McKesson never supplied A-Plus Pharmacy?

24 **A.** I'm not sure on that, sir.

25 **Q.** Well, did you see in Dr. McCann's data that they never

1 supplied?

2 **A.** I'm sure in all of that data, that data exists, but I
3 don't directly recall that. If you have something to
4 refresh my memory, I'm welcome to look at it.

5 **Q.** Sure. Let's do that.

6 Can we cull up McCann Appendix A, Page 1,056.

7 I'll just use this for demonstrative purposes, Your
8 Honor, if I may approach. I'm sorry for not asking that.

9 THE WITNESS: Thank you.

10 BY MR. SCHMIDT:

11 **Q.** Do you recognize this as a table from Dr. McCann?

12 **A.** I do.

13 **Q.** Regarding Miami-Luken -- sorry -- regarding A-Plus
14 Pharmacy?

15 **A.** Yes, up in the left-hand corner, A-Plus Pharmacy on 3
16 Chateau Lane.

17 **Q.** Who is the only supplier of A-Plus Pharmacy?

18 **A.** Miami-Luken.

19 **Q.** Did you conduct any analysis of the amount of diversion
20 in Huntington or Cabell that A-Plus Pharmacy was responsible
21 for?

22 **A.** I did not.

23 **Q.** Do you know if it was 50 percent? 90 percent?
24 99 percent?

25 **A.** I don't understand the question, sir.

1 **Q.** Do you know how much of the pharmaceutical diversion
2 you allege occurred in Huntington or Cabell County was
3 attributable to Miami-Luken -- I'm sorry -- to A-Plus
4 Pharmacy?

5 **A.** It would not be 99 percent with these numbers.

6 **Q.** Do you know how much it is?

7 **A.** I do not.

8 **Q.** Do you know if it's more or less than 50 percent?

9 **A.** It would be less than 50 percent.

10 **Q.** And how do you know that? Have you looked at their
11 orders?

12 **A.** Well, I'm looking at the numbers here.

13 **Q.** Have you looked at the actual orders to see which --
14 whether they were more or less likely to be diverted than
15 orders from other pharmacies?

16 **A.** Oh, I misunderstood your question. I thought you meant
17 in relation to the totality of distributions.

18 **Q.** No, I meant specifically diversion. Do you know how
19 much of the diversion they accounted for that you believe
20 occurred?

21 **A.** I do not.

22 **Q.** Do you know the percentage?

23 **A.** I do not.

24 **Q.** Okay. You've addressed another distributor in some of
25 your other cases; correct?

1 **A.** Possibility. Tell me who.

2 **Q.** Henry Schein.

3 **A.** I did.

4 **Q.** And do you know if Henry Schein distributed
5 prescription opioids in Huntington and Cabell?

6 **A.** I believe I recall seeing them in some of Dr. McCann's
7 charts.

8 **Q.** Is that another entity that you did not give an opinion
9 on here because the lawyers did not ask you to?

10 MR. FARRELL: Objection, Your Honor. This is
11 beginning to get cumulative again. The defendants and the
12 plaintiffs stipulated to the severance of all of the other
13 defendants as a necessary condition for remand.

14 So he's made his point that there are other
15 distributors. But to continue to blame this on the
16 plaintiffs' lawyers is a mischaracterization of the
17 procedural history of this case.

18 MR. SCHMIDT: We don't agree with the procedural
19 history, Your Honor, but it's beside the point because he
20 easily could have done it if he was doing a complete report.
21 It's relevant to what he didn't do.

22 THE COURT: I think this is proper
23 cross-examination that goes to the legitimacy and accuracy
24 of his report and is relevant and I'll overrule the
25 objection.

1 MR. SCHMIDT: Thank you, Your Honor.

2 THE WITNESS: Yes. I'm sorry. Could you repeat
3 that, Mr. Schmidt?

4 BY MR. SCHMIDT:

5 Q. Of course. Is the reason you did not give an
6 opinion here against Henry Schein because the
7 plaintiffs' lawyers didn't ask you to?

8 A. That's a correct statement, Your Honor. I was not
9 asked to.

10 Q. And, in fact, there are a total of 10 defendants in
11 other cases that you have given opinions against that you
12 did not give an opinion against here for the sole reason
13 that the plaintiff lawyers did not ask you to; correct?

14 A. That's a correct statement, Your Honor. I only gave an
15 opinion on those companies that I was asked to.

16 Q. Now, let me ask you some questions about the DEA. The
17 DEA oversees the closed system of distribution. True?

18 A. They do.

19 Q. They have an obligation to oversee all registrants who
20 handle controlled substances. True?

21 A. Yes, they do, Your Honor.

22 Q. And all those entities we've been discussing,
23 distributors, manufacturers, pharmacies, prescribers, they
24 oversee them through registration and otherwise; correct?

25 A. Through the registration process, yes, sir, and the

1 regulations.

2 **Q.** You agree with me that we as United States citizens
3 should be able to rely on the DEA to carry out their
4 obligations under the law; correct?

5 **A.** I think that's a reasonable expectation of the DEA or
6 any government entity.

7 **Q.** And those obligations include the registration and
8 re-registration of the prescribers who can write
9 prescriptions for opioids; correct?

10 **A.** That's one of the responsibilities, yes, sir.

11 **Q.** Those obligations we should be able to rely on include
12 registering and re-registering the pharmacies that dispense
13 prescription opioids; correct?

14 **A.** That's a correct statement, Your Honor.

15 **Q.** If DEA fails to exercise its obligation to oversee
16 registrants appropriately, that can result in diversion of
17 opioids. True?

18 **A.** I think generally that's an accurate statement if they
19 weren't able to do that.

20 **Q.** And in that regard, you agree that over the course of
21 the opioid statement, the DEA has probably registered,
22 issued controlled substance registrations to over a thousand
23 pill mill doctors?

24 **A.** Well, I think that possibly could be a true statement,
25 Your Honor. I don't know that they had knowledge that they

1 were pill mill doctors when they issued the registration. I
2 don't have any direct knowledge of that occurring.

3 **Q.** You would agree with that statement, sir? Yes?

4 **A.** No, I, I wouldn't agree with that.

5 **Q.** Okay. Let's -- do you recall giving testimony in front
6 of the judge in New York on August 17th, 2020, as part of a
7 *Frye* hearing?

8 **A.** Yes.

9 **Q.** Do you recall testifying truthfully in that proceeding?

10 **A.** I do.

11 **Q.** Let's cull up Page 225 of that testimony, August 17th,
12 2020. And if we could look at pages -- at lines -- this
13 appears to be the wrong page. I need page -- I might have
14 the wrong page number. Yeah, I seem to have the wrong page
15 number.

16 Let me come back to that, sir.

17 Do you agree with me that a pill mill doctor should
18 never be registered?

19 **A.** I agree with that statement 100 percent, Mr. Schmidt.

20 **Q.** And you don't agree with me that over the course of the
21 opioid epidemic, the DEA probably licensed over a thousand
22 pill mill pharmacies; correct?

23 **A.** So just so I answer that, you know, properly, if I
24 understand the question, might they have issued
25 registrations to doctors that were pill mill doctors, I

1 don't know of any where they actually had knowledge they
2 were pill mill doctors. But if it occurred through renewals
3 and situations like that, then that's a possibility.

4 **Q.** Are you aware that the DEA actually had a policy of
5 refusing to tell distributors whether or not they should
6 distribute to a given pharmacy?

7 **A.** I'm aware of I think prior to my employment that there
8 was an issue in regards to the DEA publishing a list or
9 something of that matter that caused some concern, and they
10 stopped after that point forward.

11 **Q.** So let's break that down a little bit. There was a
12 period of time prior to your employment where the DEA
13 actually told distributors, "These might be problematic
14 pharmacies." Right?

15 **A.** I don't think it was a period of time. I think an
16 employee of the DEA sent out a list.

17 **Q.** Okay. There was some point in time at which someone at
18 the DEA told distributors, "These are pharmacies you might
19 want to watch out for"?

20 **A.** More accurately, I know that it happened once, Your
21 Honor. I don't know if it was a regular occurrence or any
22 longer. But I just -- I know there was some training in the
23 academy or something came out about that incident so that it
24 didn't happen again.

25 **Q.** And do you know how many times that happened, how

1 regular a practice it was?

2 **A.** I do not.

3 **Q.** Do you know if it happened five years? Ten years?

4 **A.** Oh, I don't believe it happened that long.

5 **Q.** So how long did it happen?

6 **A.** I don't know, but I don't believe it happened for that
7 length of time, sir.

8 **Q.** Was it before your time?

9 **A.** Yes, it was.

10 **Q.** Okay. During your time, the DEA had a policy that
11 prohibits DEA investigators from calling and telling people
12 whether or not to distribute a drug or not to distribute to
13 a given pharmacy; correct?

14 **A.** That's been a long-standing rule with the DEA. We do
15 not tell -- if you're talking about a shipment, shipping,
16 there's a rule in the DEA since I've been hired that we
17 don't tell a registrant whether or not to ship.

18 We also are trained and we're told repeatedly we do not
19 tell a pharmacist whether or not to issue a prescription.
20 That's, that's, that's the decision that rests on that
21 registrant, Your Honor.

22 **Q.** That includes not telling them if you have concerns
23 about a pharmacy they're supplying. True?

24 **A.** I wouldn't say that's a fully true statement. I
25 think -- and I don't remember directly right now, but

1 there's been times when I was a DEA investigator I'd have a
2 week -- every fifth or sixth week I have a duty assignment.
3 The duty assignment is for the whole week I answer phone
4 calls from registrants all over the areas we cover.

5 So there would be times when somebody would call and
6 would have some questions; a pharmacist about a
7 prescription. I can't tell a pharmacist to fill it or not,
8 but I can generally ask some questions and discuss the
9 corresponding responsibility. And through that
10 conversation, I think the pharmacist was able to make a
11 better decision.

12 I don't remember directly with the distributor having
13 that same kind of conversation. I know I've had on-site
14 discussions about, you know, whether or not to ship. And I
15 think there's been discussions in my career where I've had
16 those similar discussions.

17 MR. SCHMIDT: Your Honor, he's answering questions
18 I'm not asking. I didn't ask about discussions with
19 pharmacists and general guidelines and issuing
20 prescriptions. I asked him a simple question about whether
21 he --

22 THE COURT: Well, just try to answer the specific
23 question.

24 THE WITNESS: Okay. I understand, Your Honor.

25 THE COURT: But he can explain his answer. So

1 there's kind of a gray area between those two propositions.

2 MR. SCHMIDT: Understood, Your Honor.

3 BY MR. SCHMIDT:

4 Q. Do you know of a time where you were investigating
5 a pharmacy and you made a point of telling the
6 distributors, "Don't ship to that pharmacy because we're
7 investigating it"?

8 A. I've never made a direct statement like that. That
9 would be against the policy of the DEA.

10 Q. If a distributor called you up and said, "Should we
11 ship to this pharmacy?" And you were conducting an
12 investigation of that pharmacy, would you tell them?

13 A. What would I tell them?

14 Q. Would you tell them that you were conducting an
15 investigation?

16 A. I would not.

17 Q. And you understand sometimes your investigations could
18 go on for years and years and years; correct?

19 A. That's a correct statement, Your Honor.

20 Q. If they called you up every month during those years
21 and years and years and said, "Should we ship to this
22 pharmacy?" You would not tell them, "We are investigating
23 this pharmacy." Correct?

24 A. I might not make that statement. I may have made some
25 other kind of statement.

1 **Q.** It would be against policy to tell them you were
2 investigating that pharmacy, true, as you understand it and
3 just articulated it two minutes ago?

4 **A.** I don't know that there's a written policy. That's
5 just kind of a standing understanding when I worked in the
6 DEA you didn't disclose an investigation.

7 But, on the other hand, to answer that question -- and
8 I don't want to go on and get in trouble again, Your Honor,
9 but if there was some public harm, the criminal
10 investigation wouldn't take precedence over public harm and
11 public safety.

12 **Q.** Are you aware of the DEA ever telling one of the
13 distributors in these cases not to distribute to a pharmacy
14 in Huntington/Cabell?

15 **A.** I'm not aware of that, no, sir.

16 **Q.** The public should be able to rely on the DEA to act on
17 suspicious orders as appropriate; correct?

18 **A.** I think that's an accurate statement, Your Honor.

19 **Q.** I'd like to show you a document that's been admitted
20 into evidence, please.

21 And just to look at this document, you've seen this
22 document before which is in evidence.

23 You can put it up on the screen, Defendants' West
24 Virginia 1597.

25 Correct?

1 **A.** Yes, you and I have discussed it before, sir.

2 **Q.** You've read it a couple of times; right?

3 **A.** We have.

4 **Q.** You've read it a couple times; correct?

5 **A.** I have.

6 **Q.** Let's turn to Page 36, please.

7 Do you understand --

8 Actually, before we get there, can we put this up on
9 the screen, please, Defendants' 1597.

10 This is a review of the Drug Enforcement
11 Administration's Regulatory and Enforcement Efforts to
12 Control the Diversion of Opioids. Do you have that
13 understanding, sir?

14 **A.** Yes.

15 **Q.** All right. Let's turn to Page 36 of this document.
16 It's the little numbers in the lower left corner.

17 And if you actually look back at Page 35, you'll see
18 that this appears in a section called "Suspicious Order
19 Reporting System." Do you see that?

20 **A.** I do.

21 **Q.** If we look at the next page, Page 36 in the lower left
22 corner, it states -- and I'll start in the middle of the,
23 the middle paragraph, please.

24 Do you see the sentence that begins "however"?

25 Let's highlight "however," please.

1 **A.** Okay. I have it. I'm sorry.

2 **Q.** Do you understand that's talking about suspicious order
3 reports from distributors?

4 **A.** I do.

5 **Q.** It says, "However, when we asked DEA field division
6 staff to locate these reports at multiple sites throughout
7 the country, staff were unaware of the requirement to
8 maintain the reports and could not locate them."

9 Did I read that correctly?

10 **A.** You did.

11 **Q.** Do you take issue with the factual truth of that
12 statement that DEA did not keep individual suspicious order
13 reports sent to field offices?

14 **A.** In the Detroit office we did.

15 **Q.** Let's cull up -- go back to your New York testimony,
16 please. Let's cull up February 7th, 2020, at Page 230,
17 lines 3 through 10.

18 And you can run the video, please.

19 February 7th, 2020, Page 230, lines 3 through 10. I'm
20 going to ask you if you recall being asked the question and
21 giving the answer.

22 (A video clip was played as follows:)

23 **Q.** "Do you take issue with the factual truth of that
24 statement that DEA did not keep individual suspicious order
25 reports sent to field offices?"

1 **A.** "I'm not sure I take exception to it."

2 (Video clip concluded)

3 BY MR. SCHMIDT:

4 **Q.** Were you testifying truthfully in that deposition,
5 sir?

6 MR. FARRELL: Objection, Your Honor. This is not
7 inconsistent with his testimony. His testimony was that --
8 related to the Detroit field office. I don't believe this
9 impeaches the witness at all.

10 MR. SCHMIDT: It absolutely does. It's directly
11 opposite to what he just said. I asked him if he took
12 exception to it and he said, "We did it in Detroit." He
13 said the exact opposite in his sworn testimony.

14 THE COURT: Overruled.

15 BY MR. SCHMIDT:

16 **Q.** Were you testifying truthfully when you gave that
17 testimony, sir?

18 **A.** I believe I am here. You know, I can't speak for
19 across the United States whether that occurred. Obviously,
20 somebody has that opinion. I'm just aware in Detroit when
21 those suspicious orders come in, we wrote a report on it and
22 documented them.

23 MR. SCHMIDT: Your Honor, I have to move to strike
24 that. That doesn't answer my question at all. I asked him
25 if he was testifying truthfully when he gave that statement.

1 THE COURT: Well, --

2 MR. FARRELL: Judge, I object to striking the
3 answer.

4 THE COURT: I'm going to deny the motion to
5 strike. I think he's explaining his answer.

6 Go ahead.

7 BY MR. SCHMIDT:

8 Q. Were you testifying truthfully, sir?

9 A. Yes.

10 Q. Okay. Now, let's go on in the report, if we can go
11 back to the report, 1597, Page 36.

12 In the next sentence that we were looking at it says,
13 "One diversion program manager described the SORS database
14 as a joke, noting the DEA field division staff did not
15 receive access to the SORS database until 2017, nearly 10
16 years after it was created." Do you see that?

17 A. I see that.

18 Q. The SORS database is the DEA's suspicious order
19 reporting system database; correct?

20 A. Yes.

21 Q. And the field offices that this sentence tells us did
22 not receive access to the database until 2017, nearly 10
23 years after it was created, they were often the agents
24 engaged in the investigations; correct?

25 A. Yes. Specifically, Your Honor, this, this speaks to an

1 on-line search database. Prior to 2017 I had requested
2 suspicious orders from headquarters, but it was a manual
3 request. You'd have to actually call and ask for someone to
4 provide them to you. I think, just for clarification, this
5 talks about a database that went on-line in 2017.

6 **Q.** Are you finished, sir?

7 **A.** Yes.

8 **Q.** Which field office had oversight of Huntington/Cabell?

9 **A.** When I was working, it was the Washington office,
10 Washington, D.C.

11 **Q.** Okay. It's true, is it not, that DEA field division
12 staff did not receive access to the SORS database until
13 2017?

14 **A.** The on-line database, that's correct.

15 **Q.** Is it a good thing that they now have access to it?

16 **A.** Sure. They probably should have had access all along.

17 **Q.** That was my next question. They should have had access
18 all along; correct?

19 **A.** Yes.

20 **Q.** Let's go to Page 20 of this document, please.

21 And I was asking you a few minutes ago about being able
22 to rely on the DEA to carry out its registration
23 responsibilities in the number of pill mill doctors. Do you
24 remember that?

25 **A.** I do.

1 **Q.** What I'd like to show you is this heading
2 "Pre-registration investigations did not adequately vet
3 applicants." Do you see that heading?

4 **A.** Yes.

5 **Q.** Let's go to the last paragraph on that page, please.

6 "According to the associate section chief of DEA's
7 regulatory section, DEA conducts pre-registration
8 inspections only on Type B registrants."

9 Do you see that?

10 **A.** I do.

11 **Q.** And that includes distributors; correct?

12 **A.** That's correct.

13 **Q.** And applicants whose registration previously had been
14 suspended or revoked. Do you see that?

15 **A.** Yes.

16 **Q.** That's a true statement; correct?

17 **A.** Yes.

18 **Q.** "Therefore, Type A registrants --" and we can carry
19 over to the next page, please -- "which include physicians,
20 dentists, and pharmacists are rarely required to undergo a
21 pre-registration investigation."

22 Do you see that?

23 **A.** Yes.

24 **Q.** True statement?

25 **A.** It's -- for clarification, are we talking --

1 Q. True statement, sir?

2 A. I just -- so I answer this correctly --

3 Q. It says, "Type A registrants, which include physicians,
4 dentists, and pharmacists are rarely required to undergo a
5 pre-registration investigation."

6 Do you take issue with the factual truth of that
7 statement?

8 A. I do --

9 Q. Okay.

10 A. -- depending on the, on the meaning of the
11 pre-registration. If they're talking about an on-site visit
12 like they are with the Type B registrants, then, then I
13 would, I would not take exception. If they're saying they
14 undergo no pre-registration investigation, I would disagree
15 with that statement.

16 Q. All right. Well, let's take a look at what they found
17 in the study on just that point. Let's go to the next
18 paragraph, please.

19 Can we cull up the next paragraph, please?

20 "During interviews --" the first full paragraph on the
21 page, please.

22 "During interviews, some field division staff expressed
23 concerns about the lack of vetting in pharmacies during the
24 pre-registration process."

25 Do you see that?

1 **A.** I do.

2 **Q.** And then it talks about how if a pharmacy sold to
3 another corporation, the new corporation could circumvent
4 the pre-registration process and DEA would have no
5 knowledge.

6 Do you see that?

7 **A.** I see that.

8 **Q.** And then let's go to the next paragraph, please.

9 "Further, we found that if a potential registrant does
10 not disclose past criminal history, suspensions,
11 revocations, or other unbecoming conduct, DEA does not
12 inquire further."

13 Do you see that?

14 **A.** I see that's what it says.

15 **Q.** Do you take issue with the factual truth of that
16 statement in this government report?

17 **A.** I can only speak on this matter, Your Honor, from my
18 experience when I was working.

19 I know they did not run criminal histories on, on
20 practitioners on licensing or applications, but I know that
21 in the Detroit divisional office there was registration
22 clerks highly competent, and they would do a pretty
23 extensive background check.

24 If that suspension or revocation was of a medical
25 license, they would check that. And if the registrant

1 applying had answered "yes" on the proper liability
2 question, or depending on what the previous violation was,
3 they would be referred for a review.

4 So I can, I can agree with you, Mr. Schmidt, on part of
5 this sentence, but there's other parts -- I think we talked
6 about this before -- I do not agree with.

7 **Q.** Did Detroit register doctors or pharmacies or dentists
8 in Huntington/Cabell?

9 **A.** They did not. And I did not know we were speaking
10 specifically about --

11 **Q.** Let's speak specifically about Huntington/Cabell.

12 **A.** Okay.

13 **Q.** Do you take issue with the truth of that statement as
14 to Huntington/Cabell?

15 **A.** I don't have any knowledge one way or another to
16 answer, Mr. Schmidt, about Cabell in regard to the
17 registration.

18 **Q.** "During interviews, several diversion investigators
19 told us that if an applicant with a valid state license does
20 not answer "yes" to the registrant applicant's liability
21 question," that you were just referring to, "as to whether
22 the applicant has had issues with previous state licenses or
23 allegations of misconduct, DEA approves the application
24 without further verification from the state medical board or
25 pharmacy board. As a result, an applicant that falsifies

1 answers on the application can fraudulently obtain a DEA
2 registration."

3 Do you see that?

4 **A.** I see it.

5 **Q.** Do you have any reason to question the truth of that as
6 to registration decisions made for Huntington/Cabell?

7 **A.** I do not.

8 **Q.** Let's look at the last sentence.

9 "Indeed, one diversion investigator told us that even
10 if an applicant answered "yes" to one or more of the
11 liability questions, some of her colleagues do not follow up
12 to determine whether the applicant should be denied a DEA
13 registration."

14 Do you see that?

15 MR. FARRELL: Objection, Your Honor.

16 THE COURT: What's the basis?

17 MR. FARRELL: Hearsay within hearsay.

18 MR. SCHMIDT: It's a report --

19 THE COURT: Well, this is cross-examination. He
20 can answer it if he can.

21 BY MR. SCHMIDT:

22 **Q.** Do you see that?

23 **A.** Yes, sir, I do see that. Is this restricted to Cabell
24 County and Huntington?

25 **Q.** I haven't asked a question. I just asked if you saw

1 it.

2 **A.** Oh, okay. I'm sorry.

3 **Q.** Do you have any reason to take issue with the truth of
4 that statement as applied to registration in
5 Huntington/Cabell?

6 **A.** I do not, sir.

7 **Q.** Do you know the DEA can use ARCOS data to determine the
8 volume of opioids supplied by all distributors to a
9 pharmacy; correct?

10 **A.** I do.

11 **Q.** They can use ARCOS data to determine the volume of
12 opioids supplied by all distributors to a county; correct?

13 **A.** I'm sorry? To a --

14 **Q.** To a county.

15 **A.** Yes.

16 **Q.** You've seen this document that we have marked as
17 Defendants' West Virginia 642; correct?

18 **A.** It looks familiar. I'm not positive.

19 **Q.** We had a chance to talk about it in your New York
20 deposition; correct?

21 **A.** I believe so.

22 **Q.** You'll remember we actually took a break from your
23 deposition so you could go and confirm on the DEA website
24 that this is, in fact, a publication available on the DEA
25 website talking about the ARCOS database; correct?

1 **A.** I recall it except I think one of the attorneys for the
2 defendants actually found it but, yes.

3 **Q.** Yes. One of my colleagues in this room found it and
4 pointed you to it and you were able to confirm that this is
5 from the DEA's website?

6 **A.** Yes. And then I was willing to discuss it, yes, sir.

7 MR. SCHMIDT: We move this into evidence, Your
8 Honor.

9 THE COURT: Any objection?

10 MR. FARRELL: Just a second, Your Honor.

11 (Pause)

12 BY MR. SCHMIDT:

13 **Q.** And to lay just a further foundation, you've read
14 the testimony of Kyle Wright as taken in the broader
15 opioids litigation; correct?

16 **A.** Yes, sir.

17 **Q.** And this is an exhibit to his deposition because it
18 was, in fact, a presentation he conducted; correct?

19 **A.** Yes.

20 MR. FARRELL: No objection, Your Honor.

21 THE COURT: It's admitted.

22 BY MR. SCHMIDT:

23 **Q.** Let's put this up on the board. It says "ARCOS
24 Automation of Reports and Consolidated Order System."
25 This is this ARCOS database we've been talking about;

1 correct?

2 **A.** Yes.

3 **Q.** And this is a presentation from 2011. If you go to the
4 second page, you'll see it's from Kyle Wright, Unit Chief
5 Targeting and Analysis. Correct?

6 **A.** Yes.

7 **Q.** You understand his roles included responsibilities
8 relating to ARCOS?

9 **A.** Yes.

10 **Q.** Let's look at Page 17, please. Let's look at actually
11 Page 16 first.

12 Do you see -- do you recall from looking at this he has
13 a --

14 **A.** I'm sorry?

15 **Q.** He has a series of sample charts showing the ability of
16 ARCOS to analyze data in different ways; correct?

17 **A.** Yes.

18 **Q.** Let's look at the first chart on Page 17. This shows
19 that you can use ARCOS, or the DEA could use ARCOS to
20 analyze trends in U.S. data across time, trends in state
21 data across time. Correct?

22 **A.** Yes.

23 **Q.** And they had the ability to look at it on a per
24 population basis; correct?

25 **A.** Yes, sir.

1 **Q.** If we go to the next page, Page 18, the DEA could use
2 ARCOS to track the distribution of specific prescription
3 opioids on a per capita basis year by year, region by
4 region; correct?

5 **A.** Yes.

6 **Q.** If we go to Page 21, please, the DEA had the ability to
7 use ARCOS data to track the distribution of individual
8 prescription opioids, this time methadone, on a county by
9 county basis. Here I think we're looking at North Carolina
10 as the example he's given. Do you see that?

11 **A.** I do.

12 **Q.** And they could actually not only look at it on a county
13 by county basis, they could determine whether a given county
14 was average, above average, below average. Correct?

15 **A.** Yes, sir, they could do that. Yes, Your Honor, they
16 could.

17 **Q.** We don't need to go through every one of these. Why
18 don't we flip ahead to -- actually, let's go to 23.

19 DEA had the ability to use this ARCOS data for both
20 investigative purposes and court, legal purposes; correct?

21 **A.** That's what this slide says, yes, sir.

22 **Q.** And just one example of that, if we go to slide 24,
23 please. They could do things like look at purchases of
24 specific prescription opioids by individual pharmacies and
25 do things like compare that to what was the state average

1 for that pharmacy, what was the U.S. average for that
2 pharmacy; correct?

3 **A.** Yes.

4 **Q.** DEA refused to allow distributors any access to ARCOS
5 data until 2018; correct?

6 **A.** I'm aware that they did not allow outside entities to
7 access that database.

8 **Q.** Including distributors; correct?

9 **A.** Everyone, yes, sir.

10 **Q.** Including distributors?

11 **A.** Including distributors.

12 **Q.** They were criticized for not providing distributors
13 with that access to ARCOS prior to 2018; right?

14 **A.** That's correct. There was some criticism, Your Honor.

15 **Q.** They were required to give distributors some access by
16 law?

17 **A.** That's a correct statement, yes, sir.

18 **Q.** And you agree that it was a good thing to give
19 distributors access to ARCOS?

20 **A.** I think generally it was a good thing. I can see some
21 potential faults or problems with it. But, overall, if it
22 prevents diversion, it's a good thing.

23 **Q.** Would it have been a good thing to do it even earlier?

24 **A.** Yes. I think anything that would have helped prevent
25 diversion --

1 THE COURT: Do you know why DEA did not permit
2 disclosure before 2018?

3 THE WITNESS: For a while, Your Honor, they used
4 to say it was proprietary. But then I, I think also they
5 felt there, there was input from distributors and
6 manufacturers, that they would use the data as a tool to go
7 in and try to see what market share was and then try to
8 take -- fight each other on, you know, where they knew that
9 they could market a product and where it was being
10 distributed. I think there was that visibility that was a
11 problem.

12 BY MR. SCHMIDT:

13 Q. They were forced to overcome those concerns and
14 grant access; correct?

15 A. I think the opioid epidemic helped them overcome those
16 concerns.

17 Q. An act of Congress helped them overcome those concerns;
18 right?

19 A. Yes.

20 Q. The DEA failed to act in that regard; correct?

21 A. I'm not sure what guidance they had to take that
22 position, but they did not act. That's an accurate
23 statement.

24 Q. Let's go back to 21, please. Do you remember talking
25 about how the DEA had the ability to look at a county by

1 county basis and determine whether that county was average,
2 above average, below average?

3 **A.** I do.

4 **Q.** Are you aware of the DEA ever looking at City of
5 Huntington or Cabell County and telling any distributor the
6 level of distribution to that county was wrong?

7 **A.** I'm not aware whether that did or did not occur, Your
8 Honor.

9 **Q.** You were asked a question about whether distributors
10 ever analyzed volume to a specific county. Did DEA, to your
11 knowledge, ever look at the overall distribution or any one
12 distributor's distribution to Huntington or Cabell County
13 and make a judgment that it should be different?

14 **A.** Not that I'm aware of, Your Honor.

15 **Q.** Was any such judgment ever communicated to any
16 distributor in this case?

17 **A.** Not that I'm aware of, Your Honor.

18 **Q.** I want to go back to the quotas for opioids that we
19 touched on earlier. And let's go back -- do you still have
20 that Office of the Inspector General report in front of you?

21 **A.** I do.

22 **Q.** Exhibit DEF-WV-1597, please. And if you could start by
23 looking at Page 7 of that document. I'm sorry, Page 12 of
24 that document, again looking at the numbers in the bottom
25 right-hand corner.

1 If you look at the numbered paragraphs, I want to ask
2 you a question about that Paragraph Number 1, please.

3 Do you see that in Number 1 they're discussing the APQ,
4 aggregate production quota or, as they refer to it in the
5 first clause, the national quota? Do you see that?

6 **A.** I do.

7 **Q.** I want to look at the second sentence if we could and
8 ask you if you have this understanding of what quota is.

9 Quote: "The maximum amounts of each basic class of
10 Schedule I and II controlled substances the DEA
11 administrator deems necessary for manufacture in a calendar
12 year by all pharmaceutical manufacturers combined."

13 And this is the part I want you to focus on:

14 "For the estimated medical, scientific, research, and
15 industrial needs of the United States or for lawful export."

16 Is that your understanding of how the quota is supposed
17 to be set?

18 **A.** I do. That is my understanding, Your Honor.

19 **Q.** And, specifically, is it your understanding that the
20 quota is supposed to be based on estimated medical need and
21 other delineated needs?

22 **A.** Yes, Your Honor, that's the criteria.

23 **Q.** Should citizens be able to rely on the DEA
24 appropriately setting quota based on medical and other
25 listed needs? Yes or no?

1 **A.** Yes, Your Honor.

2 **Q.** Let's look at Page 18, please.

3 You're aware the DEA has been faulted for not meeting
4 that trust that has been given to it in terms of setting the
5 quota; correct?

6 **A.** I'm, I'm aware that they've been criticized for their
7 handling of the quota, yes, sir.

8 **Q.** Let's look at Page 18, please.

9 Do you see that -- if we cull out the first paragraph,
10 please.

11 In the second sentence it talks about the rising opioid
12 overdose death rate. Do you see that?

13 **A.** I do.

14 **Q.** And then in the next sentence it says, "Yet, from 2003
15 to 2013, DEA authorized manufacturers to produce substantial
16 amounts of opioids."

17 And then it gives an example. "For example, the
18 aggregate production quota, APQ, of oxycodone in the U.S.
19 increased over 400 percent from 34,482 kilograms in 2002 to
20 a high of 153,750 kilograms in 2013."

21 Do you see that?

22 **A.** I do.

23 **Q.** And you're aware that that's factually true?

24 **A.** I don't dispute it. I, I don't know that that's, you
25 know, a, a factual statement. I don't have any reason to

1 not believe it either, Your Honor.

2 **Q.** And if we look at the next page, it actually shows us
3 the amount by which the quota has gone up. Do you see that?

4 **A.** I do.

5 **Q.** As the plaintiffs' diversion control investigations
6 expert in this case, do you take any issue with the numbers
7 in this report regarding the DEA's quota?

8 **A.** I think it bears some scrutiny, but I wasn't present
9 when they -- I don't know what material they reviewed. I
10 don't know how those decisions were made. I know we
11 discussed it before.

12 I, I have some concerns about just whacking the quota.
13 I think that's what it was called for for a period of time.
14 But, obviously, with the opioid epidemic raging, I'm not
15 sure raising it is, was the most prudent. But it's
16 difficult for me to give you an opinion when I wasn't
17 actually involved with that decision-making, Mr. Schmidt.

18 **Q.** All I was asking you was do you take issue with these
19 numbers?

20 **A.** I do not.

21 **Q.** Okay. Let's look back at the page we were looking at,
22 Page 18.

23 **A.** Okay.

24 **Q.** In the second paragraph it says, "However, it was not
25 until 2017 that then acting DEA administrator Chuck

1 Rosenberg reduced the APQ for most controlled substances,
2 including oxycodone, by 25 percent."

3 Do you see that?

4 **A.** I do.

5 **Q.** And if we look at the next page, you can see that
6 illustrated graphically. Do you see that?

7 **A.** I do.

8 **Q.** Do you take any issue with the factual accuracy of
9 that?

10 **A.** I do not.

11 **Q.** Now, maybe you touched on this in that other answer.
12 Was it a good thing that the DEA reduced the quota?

13 **A.** I think it's a good thing as long as they monitor to
14 make sure that cutting the quota didn't deprive people who
15 legitimately needed the medication to receive it.

16 And I say that because if you can start to diminish the
17 diversion, then it's okay to cut the quota. But just
18 cutting the quota and there's a problem in America, you
19 know, one of the unintended consequences is always a concern
20 that people that need drugs don't get them.

21 **Q.** Okay. If you impose arbitrary limits, you might impact
22 diversion, but you might also keep it from people who need
23 it; correct?

24 **A.** That's, that's my point, yes, sir.

25 **Q.** And that's true at the DEA; correct?

1 **A.** I just think that --

2 **Q.** In terms of their quota. I'm sorry.

3 **A.** Pardon me?

4 **Q.** In terms of their quota.

5 **A.** I just think it's -- I think it's a by-product of
6 taking an act without realizing what the consequences are.
7 You know, it's -- if depriving people who need opioids
8 legitimately so that there's less diversion, I, I -- you
9 know, that's a decision that people way above where I was in
10 the DEA made, but it's a concern to me because, you know,
11 they're important medications for some people.

12 **Q.** That would be a concern for distributors too. If they
13 arbitrarily imposed limits on prescription opioids, that
14 could also deprive medication from people who needed it.
15 True?

16 **A.** I hope it's a concern for everyone. I hope there's not
17 somebody that would say, "I don't want people to be able to
18 obtain medication."

19 **Q.** Is what I said true, sir?

20 **A.** Yeah, it's true.

21 **Q.** Thank you. If we look at the heading -- let's go back
22 to 17.

23 Just -- not less than two years ago, the heading on
24 this page, the OIG was concluding DEA was slow to respond to
25 the dramatic increase in opioid abuse and needs to more

1 fully utilize its regulatory authorities and enforcement
2 resources to detect and combat the diversion of controlled
3 substances.

4 Do you see that?

5 **A.** Yes.

6 **Q.** Do you take any issue with that conclusion?

7 **A.** No, because as I stated earlier, I think everybody that
8 plays a role in preventing the opioid crisis or its
9 standing, you know, I don't think they're immune from
10 criticism.

11 **Q.** Now, we've, we've covered a range of different entities
12 that you say played some role in causing the opioid crisis;
13 doctors, pharmacies, manufacturers, distributors not present
14 here, DEA.

15 You're not offering an opinion on the full ranges of
16 the causes of the opioid crisis in Huntington or Cabell
17 County. True?

18 **A.** I am not, sir. Those -- some of those are my personal
19 opinions based on my work experience.

20 **Q.** And the reason you're not able to offer opinions on all
21 the causes of the opioid crisis in Huntington/Cabell County
22 is because you didn't look at all the participants in the
23 supply chain, all the participants involved in prescription
24 opioids and illegal conduct within Huntington/Cabell.
25 Correct?

1 **A.** Could you say that one more time? I'm sorry.

2 **Q.** The reason that you're not able to offer opinions on
3 all the causes of the opioid crisis in Huntington and Cabell
4 is because you didn't evaluate all of the participants.
5 Correct?

6 **A.** You're talking about registrants outside or entities
7 outside of distributors, I didn't evaluate all of those
8 entities?

9 **Q.** I'm talking about entities outside of the three
10 distributors in this case that the plaintiff lawyers asked
11 you to look at. You didn't look at any of them; correct?

12 **A.** I did not look at them, no, sir.

13 **Q.** And you would agree that at a minimum, thousands of
14 people and companies contributed to the opioid crisis in
15 Cabell County in your view?

16 **A.** I don't know if it's thousands, but it's a considerable
17 amount of people.

18 **Q.** Let's cull up Mr. Rafalski's testimony from
19 September 11th, 2020, Page 73, lines 1 through 15, please.
20 Let's put it up on the screen. 73, please.

21 At the top of the page, line 1, I asked you, "Between
22 those hundreds -- I take it between those different groups
23 you would agree with me that we're into the hundreds if
24 we're talking about manufacturers, doctors, pharmacies,
25 diverters, distributors?"

1 You say, "That's a very broad spectrum, but I would say
2 it would probably be higher than the number you quoted."

3 And then the next question, I asked, "Okay. Maybe into
4 the thousands?"

5 Answer: "Well, if you're just talking generally
6 diverters, people that passed, depending on if we are using
7 the broad definition or we're using the diversion the DEA,
8 my definition, broad definition I would say it's in the,
9 it's minimally in the thousands." Did I read that
10 correctly?

11 **A.** I did.

12 MR. FARRELL: Objection, Your Honor. This is not
13 inconsistent with what the witness just said.

14 THE COURT: Well, I think it's directly
15 inconsistent with what he just said.

16 MR. FARRELL: Maybe I misheard the line of
17 testimony, but I don't, I don't believe that his testimony
18 was a definitive statement one way or the other.

19 MR. SCHMIDT: We have the record, Your Honor. It
20 was.

21 THE COURT: Yeah. I've lost the statement here on
22 the monitor, but I was reading it very carefully and I think
23 this is inconsistent with his, with his statement. I don't
24 know -- well, I'll leave it at that. Your objection is
25 overruled, Mr. Farrell.

1 BY MR. SCHMIDT:

2 Q. Sir, just to round this line of questions out, you
3 agree that it's important that an expert serve as an
4 expert and not an advocate?

5 A. I do.

6 Q. You should make decisions based on the facts and not be
7 partial to either side?

8 A. I agree with that statement, Your Honor.

9 Q. It would be improper just to be a mouthpiece for the
10 lawyers and say whatever they want you to say; correct?

11 A. That's a correct statement. I agree with that, Your
12 Honor.

13 Q. Are there any opinions you gave in this case that the
14 lawyers did not ask you to give?

15 A. The opinions in the report are my opinions.

16 Q. Are there any opinions you gave in this case that the
17 lawyers did not ask you to give?

18 A. They didn't ask -- they asked me to just conduct my
19 review of the documents and materials and to provide my
20 opinion. They didn't ask me to give a particular opinion or
21 not to give a particular opinion.

22 Q. Could we cull up the September 11th, 2020, transcript,
23 line 81:23 to 82:1.

24 Do you see where you were asked at the bottom of the
25 page, line 23 -- let's just start with line 23, please.

1 We're going to need to carry over to the next page.

2 Do you see where you were asked the question I just
3 asked you twice. "Are there any opinions you gave in this
4 case that the lawyers did not ask you to give?"

5 Your answer: "No, sir."

6 Did I read that correctly?

7 **A.** You did.

8 **Q.** Were you being truthful?

9 **A.** Yes.

10 **Q.** You never told the plaintiff lawyers that you would not
11 give any of the opinions they asked you to give; correct?

12 **A.** I guess I don't understand the question.

13 **Q.** Let me rephrase it then. Are there any opinions that
14 the lawyers asked you to give that you said, "No, I can't
15 give this opinion"?

16 **A.** That's -- no, that did not occur.

17 THE COURT: I think there's a difference between
18 asking him for a specific opinion and asking him to give an
19 opinion on a subject. And I don't think your question, Mr.
20 Schmidt, is fair to the witness without straightening that
21 out.

22 MR. SCHMIDT: Okay.

23 THE COURT: And if I'm confused, you can
24 straighten me out.

25 MR. SCHMIDT: Well, I think what I'm trying to

1 point out is not that they wrote the opinions for them that
2 has actually occurred in other litigation.

3 My question, though, is -- he's only giving opinions on
4 who he's been asked to give. He's not giving opinions on
5 anything else. And there's no opinions they asked him to
6 give that he said "no" to.

7 Those are the only points I was covering and I think
8 that's what he testified to. And I think that is
9 methodologically relevant.

10 THE COURT: Okay.

11 MR. SCHMIDT: Thank you, Your Honor.

12 BY MR. SCHMIDT:

13 Q. Let me switch gears, Mr. Rafalski.

14 I want to show you a document that you've seen before,
15 another one of these government reports if I could.

16 Could I get Defendants' West Virginia 1598.

17 MR. SCHMIDT: May I approach, Your Honor?

18 THE COURT: Yes.

19 THE WITNESS: Thank you.

20 MR. SCHMIDT: May I have one minute to confer,
21 Your Honor?

22 THE COURT: Uh-huh.

23 (Pause)

24 BY MR. SCHMIDT:

25 Q. Sir, do you remember talking a moment ago just

1 before we got into this document about DEA being
2 criticized for not sharing ARCOS data with distributors
3 and then that law passing to require them to share that
4 data?

5 **A.** I do, Your Honor.

6 **Q.** What's your understanding of why they were criticized?

7 **A.** Because denying them that data would also deny the
8 distributors the chance to have further information and make
9 decisions.

10 **Q.** Why would that be useful?

11 **A.** Well, because any amount of data or increased amount of
12 data to prevent diversion would be a good thing.

13 **Q.** And that's why you think it's a good thing that
14 distributors now have access to some form of that data;
15 correct?

16 **A.** Yes, but -- yes, Your Honor.

17 **Q.** Let's look at Defense West Virginia 1598. You've seen
18 this document before; correct?

19 **A.** I have.

20 **Q.** In fact, we've spent some time looking at it; correct?

21 **A.** We have.

22 **Q.** Do you recognize that this is a government report from
23 the government accountability office; correct?

24 **A.** Yes, sir.

25 **Q.** Just from January of last year, a little more than a

1 year ago, over a year ago; correct?

2 **A.** Yes.

3 MR. SCHMIDT: Your Honor, we move Defense West
4 Virginia 1598 into evidence.

5 THE COURT: Any objection?

6 MR. FARRELL: None, Your Honor.

7 THE COURT: All right. It's admitted.

8 BY MR. SCHMIDT:

9 **Q.** All right. This report is called Drug Control,
10 Actions Needed to Ensure Usefulness of Data on
11 Suspicious Opioid Orders.

12 And I'd like to look at Page 11 of the document looking
13 in the lower left-hand corner. There's a diagram called
14 Figure 1 on the document.

15 Mr. Reynolds, I don't know if it's worth doing, but if
16 there's a way to blow up the diagram with the feed that
17 appears under it, that might be useful.

18 So I want to just go through what we're looking at on
19 this image. You've had a chance to study this specific
20 image before; correct?

21 **A.** I've seen it before. I don't know if I've studied it.

22 **Q.** Well, we spent some time talking about it in your
23 deposition; correct?

24 **A.** We did.

25 **Q.** It says --

1 MR. SCHMIDT: May I approach the board, Your
2 Honor?

3 THE COURT: Yes.

4 BY MR. SCHMIDT:

5 Q. Figure 1, the prescription drug supply chain and
6 examples of opportunity for abuse and diversion. Do you
7 see that?

8 A. I do.

9 Q. And you understand that this is talking about different
10 places in the system where abuse and diversion can occur,
11 including different types of abuse and diversion; correct?

12 A. Yes.

13 Q. Let's just orient ourselves to what this covers. It
14 covers manufacturers. Do you see that?

15 A. Yes.

16 Q. Distributors with the truck? Do you see that?

17 A. Yes.

18 Q. Pharmacies?

19 A. I see that, Mr. Schmidt.

20 Q. And then the patients with doctors above the patient.
21 Do you see that?

22 A. I see that also, Your Honor.

23 Q. And then if you look at the keys, at the key down at
24 the bottom, it tells us that these boxes with the green
25 dotted lines around them are examples of where prescription

1 drug diversion can occur. And there are four of those boxes
2 showing examples of where prescription drug diversion can
3 occur. Correct?

4 **A.** That's what this chart says, yes, sir.

5 **Q.** The blue boxes, which include distributors, are
6 examples of the legitimate flow of prescription drugs. Do
7 you see that?

8 **A.** Yes.

9 **Q.** Now, if we focus on distributors, there's one dotted
10 line to a diversion area coming off of distributors. Do you
11 see that?

12 **A.** I do.

13 **Q.** And it lists three bullets in that box. Do you see
14 that?

15 **A.** I do.

16 **Q.** The first is robbery or theft from manufacturers,
17 distributors, pharmacies. That's a form of diversion that
18 can occur from distributors; correct? Robbery, theft?

19 **A.** Yes.

20 **Q.** Are you aware of any of that that's impacted
21 Huntington/Cabell relating to any of the distributors here?

22 **A.** I'm not aware of any robberies or thefts from
23 registrants in Cabell or Huntington, sir.

24 **Q.** That's the only one that applies to distributors;
25 correct?

1 **A.** That's correct, Your Honor. That's the only one.

2 **Q.** If we look at the other ones in this box, including
3 patients, those are both crimes or potential crimes;
4 correct?

5 **A.** Yes, sir, Your Honor.

6 **Q.** Let's go to the top right box. That's patients
7 engaging in doctor shopping. Do you see that?

8 **A.** I do.

9 **Q.** And then the box below is patients may provide
10 legitimately obtained drugs to friends or family for free;
11 correct?

12 **A.** I see that one also.

13 **Q.** Sometimes referred to as diversion from the medical
14 cabinet; correct?

15 **A.** Yes.

16 **Q.** And then another opportunity in the upper left is
17 healthcare providers participating in criminal drug
18 diversion schemes. Do you see that?

19 **A.** I do.

20 **Q.** All of those activities that we just looked at on that
21 diagram are crimes or potential crimes; right?

22 **A.** Yes, they are, Your Honor.

23 **Q.** And with the exception of that one example we talked
24 about that you don't know of ever happening here involving
25 distributors, none of those other ones involve distributors;

1 correct?

2 **A.** According to this chart, they do not.

3 **Q.** Okay. So let's go back to that first -- that -- this
4 type of diversion, patients may provide legitimately
5 obtained drugs to friends or family for free. That's that
6 concept of medicine cabinet diversion.

7 You agree that when a patient misuses medication that
8 was prescribed for a legitimate medical use, whether it's
9 giving it away or selling it, the patient is responsible for
10 that?

11 **A.** Yes, sir.

12 **Q.** And you have seen statistics indicating that more than
13 three out of four people who use or misuse prescription
14 painkillers use drugs prescribed to someone else; correct?

15 **A.** I see some statistics. I don't remember that exact
16 number. But I'm not going to, you know, say that I don't
17 believe that number. I just don't have a full recollection
18 of that exact number.

19 **Q.** And, in fact, you don't take issue with that statistic,
20 do you?

21 **A.** No, I do not.

22 **Q.** In the course of your work regarding diversion and
23 serving here as the plaintiffs' diversion control expert,
24 have you reviewed CDC publications on levels of diversion
25 and which ones of these types of diversion are actually seen

1 in the real world?

2 **A.** I believe I reviewed them. I don't recall what the
3 results of the review was, --

4 **Q.** Let me show you the --

5 **A.** -- were.

6 **Q.** -- CDC publication and tell me if this is one of the
7 ones you've seen before.

8 MR. SCHMIDT: Sorry, Judge. May I approach?

9 THE WITNESS: Thank you.

10 BY MR. SCHMIDT:

11 **Q.** I've put in front of you a document, MC-WV-2096.

12 Do you see the CDC logo in the bottom right corner?

13 **A.** I do.

14 **Q.** Do you see the heading "Policy Impact Prescription
15 Painkiller Overdoses"?

16 **A.** I do, Your Honor.

17 **Q.** And if we turn to Page 7 of the document --

18 MR. SCHMIDT: Actually, why don't I go ahead and
19 move this into evidence, Your Honor?

20 THE COURT: Any objection?

21 MR. FARRELL: I'm not sure, Judge. I'm trying to
22 find the author and the date.

23 MR. SCHMIDT: The author is the CDC, Your Honor.
24 The date is November, 2011 on the last page.

25 MR. FARRELL: No objection to this.

1 MR. SCHMIDT: Thank you.

2 THE COURT: It's admitted.

3 MR. SCHMIDT: Let's go ahead and put it up on the
4 screen. If we could go to the second page of the document,
5 please.

6 BY MR. SCHMIDT:

7 Q. Do you see it's got a heading called "Where the
8 Drugs Come From"?

9 A. I do.

10 Q. And the last sentence of that paragraph says, "More
11 than three out of four people who misuse prescription
12 painkillers use drugs prescribed to someone else."

13 Do you see that?

14 A. Yes.

15 Q. Do you take any issue with that, with that statistic?

16 A. No, I do not. That's I think a little different than
17 the previous one. I think the previous one was more
18 directed at family members and friends.

19 Q. You agree that when a prescription is legitimately
20 written and dispensed, distributors have no control over
21 what happens to it after that point?

22 A. That's a correct statement. I agree with that, Your
23 Honor.

24 THE COURT: We probably ought to take a break when
25 you get to a stopping point. Is this a good place?

1 MR. SCHMIDT: This is that point, Your Honor.

2 THE COURT: All right. Let's be in recess for 10
3 minutes.

4 (Recess taken at 3:12 p.m.)

5 THE COURT: You may resume, Mr. Schmidt.

6 MR. SCHMIDT: Thank you.

7 BY MR. SCHMIDT:

8 Q. Mr. Rafalski, let me pick up where we were. Do you
9 have in front of you the CDC publication MCWV-2096?

10 A. I do, sir.

11 Q. Let me just go back to Page 7. I'm told I read it into
12 the record wrong. Is the statistic they provide on Page 7
13 the following: Quote, more than three out of four people
14 who misuse prescription pain-killers use drugs prescribed to
15 someone else? Is that the quote?

16 A. Yes.

17 Q. And you take no issue with that?

18 A. I do not.

19 Q. All right. I want to come to your flagging
20 methodologies. And before I come to your flagging
21 methodologies, I'm just going to ask you general questions
22 about the obligations that distributors have; fair?

23 A. Yes.

24 Q. Distributors have a duty to report all their sales to
25 the DEA for the DEA's ARCOS database, correct?

1 **A.** All the ARCOS required drugs.

2 **Q.** Yes. And you agree that ARCOS uniquely has access to
3 all of the data submitted by each DEA registrant across the
4 country?

5 **A.** I'd agree with that, Your Honor.

6 **Q.** ARCOS is compiled by DEA in accordance with law,
7 correct?

8 **A.** Yes, sir.

9 **Q.** It's used for developing quota?

10 **A.** That's correct, Your Honor.

11 **Q.** It's used for analyzing distribution trends?

12 **A.** That's correct a statement, Your Honor.

13 **Q.** It's used for internal audits?

14 **A.** Internal audits?

15 **Q.** Yes, sir.

16 **A.** Can you define that a little further for me?

17 **Q.** Sure.

18 MR. SCHMIDT: Could we put up the expert report
19 from Mr. Rafalski in this case, P-42216, just for
20 demonstrative purposes, and go to Page 17? P-42216, please.
21 Now -- this is the wrong tab. It should be Tab 18. There
22 we go. Could we look at Page 17, please? And could we cull
23 out the second paragraph, please?

24 BY MR. SCHMIDT:

25 **Q.** This is what I was reading to you from, sir. Do you

1 see that it states the ARCOS DADS system uniquely has access
2 to all of the data submitted by each DEA registrant across
3 the country?

4 **A.** I see that paragraph and I see what part you're
5 speaking of, yes, sir.

6 **Q.** And then it says the data is compiled by DEA in
7 accordance with law. Do you see that?

8 **A.** I see that statement.

9 **Q.** Is that accurate?

10 **A.** Yes, sir.

11 **Q.** DEA uses it for inspections, correct?

12 **A.** Yes.

13 **Q.** They use it for investigations, correct?

14 **A.** That's correct.

15 **Q.** And they use it for other analyses, as well, correct?

16 **A.** That's correct.

17 **Q.** You're aware that Dr. McCann confirmed through his work
18 that the distributors in this case reported all of their
19 sales into DEA's ARCOS database, all of their required
20 sales, between 2006 and 2014?

21 **A.** Except, I believe, there was a gap of data, I believe,
22 for Cardinal for a short period of time.

23 **Q.** Okay. And did you see his testimony where he explained
24 that that could have been due to a recordkeeping issue on
25 the DEA side?

1 **A.** Yes. I'm just trying to answer your question
2 accurately, sir.

3 **Q.** And you don't take any issue with Dr. McCann's
4 conclusion that the ARCOS data received from the defendants
5 in this case is reliable, do you?

6 **A.** I do not take an exception to that, Your Honor.

7 **Q.** Distributors also have a duty to report suspicious
8 orders to the DEA, correct?

9 **A.** Yes, sir, when discovered.

10 **Q.** And let's -- let's take a look at that definition. I
11 think this is a regulation, so I think the Court can take
12 notice of it without me moving it in as an exhibit.

13 So, if I may just put it up on the screen, please.

14 It's DEF-WV- 2254. And this is the regulation as quoted
15 from the DEA website.

16 And if we could just cull out A paragraph. Actually,
17 that's the wrong paragraph. I'm sorry.

18 THE COURT: Is there any objection to me taking
19 judicial notice of this, Mr. Farrell?

20 MR. FARRELL: Not that I can think of.

21 MR. SCHMIDT: Let's cull up Paragraph B, please.

22 THE COURT: Well, I want to give you the
23 opportunity.

24 MR. FARRELL: This is -- this is -- this is the
25 CFR, correct?

1 MR. SCHMIDT: Yes.

2 THE COURT: It's judicially noticed.

3 BY MR. SCHMIDT:

4 Q. And do you see it defines suspicious orders and the
5 last sentence here is orders of unusual size, orders
6 deviating substantially from a normal pattern, and orders of
7 unusual frequency? Do you recognize that as the regulatory
8 definition of a suspicious order?

9 A. That's what the regulation says, yes, sir.

10 Q. Are you aware that this -- how long has this regulation
11 been in place?

12 A. 1971, Your Honor.

13 Q. Are you aware that just in the last year the DEA has
14 proposed amending this regulation?

15 A. I am.

16 Q. Are you aware that the subject of the proposed DEA
17 amendment is including in the regulation a do not ship
18 requirement?

19 A. I am.

20 Q. Are you aware that another subject of the proposed
21 amendment is including in the text of the regulation
22 provisions regarding recordkeeping?

23 A. I'm aware of that, also.

24 Q. There's no express reference in this definition of a
25 suspicious order to likely diversion, is there?

1 **A.** Well, it's my belief, Your Honor, the word suspicious
2 is suspicious of the diversion, although I do agree with Mr.
3 Schmidt it does not say that, but it's what it's suspicious
4 of.

5 **Q.** And that's -- that phrase you just used, suspicious of
6 diversion, that phrase appears nowhere in here?

7 **A.** That's correct.

8 **Q.** Instead, it refers to orders of unusual size,
9 frequency, pattern, correct?

10 **A.** I think that qualifies some of the things that -- that
11 may define it.

12 **Q.** And you're aware that there are all kinds of
13 circumstances when an order can be of unusual size, pattern
14 or frequency, but not be diverted?

15 **A.** That's a correct statement. I agree with that, Your
16 Honor.

17 **Q.** One example of that is a pharmacy might have a Cancer
18 Center open nearby and suddenly they have an unusual
19 pattern, orders of unusual size, or orders of an unusual
20 frequency, right?

21 **A.** That's correct.

22 **Q.** That could show up as a suspicious order even though
23 none of them are being diverted, correct?

24 **A.** Ultimately, if due diligence was done, that would be a
25 conclusion that a distributor could come to, that's correct.

1 **Q.** Another example, a pharmacy could be across the street
2 from another pharmacy that closes and so, all of that closed
3 pharmacy's customers start coming to the pharmacy that's
4 still open, correct?

5 **A.** Yes. That's another scenario, although that -- that
6 also has some potential issues that would have to be
7 resolved, but I don't disagree with that statement.

8 **Q.** And all I'm asking you, sir, is that can be an instance
9 where an order looks like it has unusual size, frequency or
10 pattern, but there's no diversion, correct?

11 **A.** That's a possibility, yes, sir.

12 **Q.** And do you have any idea, have you seen any studies
13 that tell us how many of the orders that meet this
14 definition are actually diverted?

15 **A.** Well, I know there's a comment in the new proposed
16 rule. Other than that, I've never seen anything that gave
17 an approximation.

18 **Q.** Do you know if you take the body of suspicious orders
19 that have occurred over time how many of them are actually
20 diverted?

21 **A.** I don't know that, no, sir. I don't know that, Your
22 Honor.

23 **Q.** Do you know if it's above or below five percent, ten
24 percent?

25 **A.** I don't know, Your Honor.

1 **Q.** Let me focus on some of the numbers that you showed the
2 Court. I tried to count the numbers of Suspicious Order
3 Reports you identified in your 2007-2008 time period and I
4 got 416 from all three defendants. Does that sound right?

5 **A.** Yes, sir.

6 **Q.** Including 79 from McKesson?

7 **A.** That's correct.

8 **Q.** And that's even though you didn't count any DU45s for
9 McKesson from before 2007, correct?

10 **A.** That's correct.

11 **Q.** Can you -- whether it's those pre-2007 orders or any of
12 the orders you identified, can you point to any action DEA
13 took on any suspicious order that McKesson, Cardinal or ABDC
14 made for Cabell County or Huntington?

15 **A.** I cannot, Your Honor.

16 **Q.** You're not aware of any Suspicious Order Reports
17 regarding pharmacies in Huntington or Cabell that led to any
18 investigation by DEA, correct?

19 **A.** I am not, Your Honor, although I didn't review or look
20 to determine that, but I'm not independently aware of that.

21 **Q.** You can't point me to any orders that any one of these
22 three defendants shipped into Huntington or Cabell where the
23 DEA came to them and said you should not have shipped that
24 specific order, correct?

25 **A.** That's a true statement. I didn't -- do not know that,

1 Your Honor.

2 **Q.** Are you aware that since 2007 and 2008, ABDC, Cardinal
3 and McKesson have blocked orders that go above specific
4 thresholds?

5 **A.** I'm aware of that, those changes upon that time period,
6 yes, sir.

7 **Q.** How many have they blocked?

8 **A.** I don't recall.

9 **Q.** Do you recognize it's hundreds of thousands nationwide?

10 **A.** I didn't look at nationwide.

11 MR. FARRELL: Objection, Your Honor, geographic
12 scope.

13 THE COURT: Overruled.

14 THE WITNESS: I do not know, Mr. Schmidt.

15 BY MR. SCHMIDT:

16 **Q.** Do you know how many it is in West Virginia?

17 MR. FARRELL: Objection, Your Honor, on the same
18 basis.

19 THE COURT: Overruled.

20 THE WITNESS: I do not.

21 BY MR. SCHMIDT:

22 **Q.** Do you know how many it is in Huntington-Cabell?

23 **A.** In the totality, I do not.

24 **Q.** You would agree that if you block an order, that
25 obviously keeps it from being distributed and it would not

1 lead to diversion, correct?

2 **A.** Say one more time. I'm sorry.

3 **Q.** If you block an order, that would obviously keep it
4 from being distributed and it would not lead to diversion?

5 **A.** That's a correct statement, Your Honor. I agree with
6 that.

7 **Q.** Blocking the order of opioid pills before shipment is
8 what prevents diversion from occurring, correct?

9 **A.** Yes, Your Honor, that's what prevents it.

10 **Q.** You'd agree that not reporting the suspicious order to
11 DEA is not what causes diversion, correct?

12 **A.** That -- I agree with that statement, Your Honor.

13 **Q.** Now, let's talk about your flagging methodologies.
14 You've performed them -- you showed some pretty big numbers
15 in those methodologies; do you remember that?

16 **A.** Yes, I remember. There were big numbers.

17 **Q.** Some of them were 80-90 percent, correct?

18 **A.** That's correct.

19 **Q.** You've performed those across various jurisdictions,
20 correct?

21 **A.** I performed them for Cabell County and for Huntington,
22 City of Huntington. Is that your question?

23 **Q.** No. And for Cuyahoga County. And for Summit County.

24 **A.** Oh.

25 **Q.** And for Nassau County. And for Suffolk County. And

1 for two counties in the State of Iowa; correct?

2 **A.** That's -- that's accurate. I thought we were talking
3 --

4 MR. FARRELL: Objection, Your Honor. Objection,
5 Your Honor, compound.

6 THE COURT: Sustained. You can break it up.

7 BY MR. SCHMIDT:

8 **Q.** You performed it for Cuyahoga County?

9 **A.** I did.

10 **Q.** You performed it for Summit County?

11 **A.** I did, Your Honor.

12 **Q.** You performed it for Nassau County?

13 **A.** I did, Your Honor.

14 **Q.** Performed it for Suffolk County?

15 **A.** Yes, I did, Your Honor.

16 **Q.** You performed it for two counties in the State of Ohio
17 where you're going to go give testimony in two weeks
18 regarding pharmacies?

19 **A.** That's correct, Your Honor.

20 **Q.** And every one of those analyses, you always get similar
21 numbers to what you get here, right?

22 **A.** They're high numbers. I don't -- I don't remember -- I
23 don't recall if they're -- how close they are to being
24 similar, but they're all high numbers. I agree with that
25 statement.

1 Q. Sometimes, even a hundred percent, right?

2 A. I don't recall one at a hundred percent.

3 Q. You don't recall that the case you're going to testify
4 in has a hundred percent?

5 A. I don't have a direct recollection of that.

6 Q. Can you identify any jurisdiction or any one of the
7 more than a dozen defendants you've testified against or,
8 frankly, any distributor where you could run your analyses
9 and not get similarly high numbers?

10 A. Well, since I've run it and I've got those numbers,
11 then I -- I can't identify them all.

12 Q. In terms of how your methodologies were implemented,
13 each of the six methodologies were performed by Dr. McCann;
14 true?

15 A. Yes.

16 Q. You did not speak to Dr. McCann about those analyses
17 before you used them for the first time in your first report
18 in Cuyahoga and Summit County, correct?

19 A. That's accurate. I relayed my requests through
20 plaintiffs' counsel.

21 Q. Dr. McCann did not provide you with a copy of his
22 computer code for you to review; correct?

23 A. He did not, but if he did, Your Honor, I probably
24 wouldn't have known -- it wouldn't have been usable to me.
25 I wouldn't have known the code, but that's a correct

1 statement.

2 **Q.** In fact, you didn't discuss his computer algorithms
3 with him until after you had already relied on his reports,
4 on his results for your reports in Cabell, Ohio and New
5 York, correct?

6 **A.** I -- I don't recall when we had a conversation, if I
7 discussed it with him before those two or not. I know I
8 discussed some -- had some discussions with him. I don't
9 believe so, but I don't recall directly.

10 **Q.** Would it help to show you your testimony on that?

11 **A.** Sure, that would.

12 **Q.** Okay. Do you recall that your report in this case was
13 dated August 3rd, 2020?

14 **A.** Pardon me?

15 **Q.** Do you recall that your report in this case was dated
16 August 3rd, 2020?

17 **A.** Yes. Yes, sir.

18 **Q.** And your report in New York was before that?

19 **A.** Yes.

20 **Q.** And your report in Ohio for Cuyahoga and Summit County
21 was before that?

22 **A.** That's correct.

23 MR. SCHMIDT: Can we cull up the September 1st,
24 2020 transcript at 101:11-14?

25 BY MR. SCHMIDT:

1 Q. Oh, I'm sorry. Actually, I was going to show you Dr.
2 McCann's testimony. If Dr. McCann testified that you did
3 not talk to him before those three reports, would you take
4 issue with him?

5 A. I wouldn't -- I'm not going to dispute what he said. I
6 know I had a conversation with him about some concerns, not
7 concerns, but about some assumptions, and I don't recall
8 exactly when that conversation occurred, at what point in my
9 reports.

10 Q. You didn't check the math on any of the six
11 methodologies, correct?

12 A. I did not.

13 Q. You don't know the assumptions Dr. McCann made when
14 coming up with this code to run the methodologies, correct?

15 A. I did have a discussion with him about those
16 assumptions. That's the conversation I'm talking about.

17 Q. That conversation was August 29th, 2020; correct?

18 A. That's a possibility.

19 Q. Would it help to see Dr. McCann's testimony on that?

20 A. If -- yes, if you want me to confirm that, I can.

21 Q. Okay. Let's cull up Dr. McCann's testimony,
22 September 1st, 2020 at 101, Lines 11-14. Do you see where
23 Dr. McCann testifies before your August 29th, 2000
24 discussion -- 2020 discussion with Mr. Rafalski, did you
25 discuss your computer algorithms with him? Answer, I did

1 not, no. Do you see that?

2 **A.** I see that, Your Honor.

3 **Q.** Do you have any reason to take issue with that?

4 **A.** I do not.

5 **Q.** And to confirm, this is after your August 2nd, 2020
6 report in this case, correct?

7 **A.** Yes, sir, Your Honor.

8 **Q.** Thank you. Are you aware that Dr. McCann testified
9 that he had to make certain design choices to operationalize
10 the methodologies?

11 **A.** I am.

12 **Q.** Are you aware that he had to make several choices to
13 the design of his computer algorithm?

14 **A.** Yes, I am.

15 **Q.** And you're not familiar with all the design choices Dr.
16 McCann made when coming up with his code for his
17 methodologies?

18 **A.** I -- I think I discussed them all with him. Whether I
19 have recollection of all of them, no, but I don't think that
20 -- as far as I'm aware, I don't think he didn't tell me any.

21 **Q.** When we talked in your deposition, you weren't able to
22 tell me all the assumptions he made, correct?

23 **A.** That's correct. And I wouldn't be able to tell you
24 right now either.

25 **Q.** Thank you. Now, I want to --

1 MR. SCHMIDT: If I may approach the board, Your
2 Honor? May I approach?

3 THE COURT: Yes.

4 MR. SCHMIDT: Thank you.

5 BY MR. SCHMIDT:

6 Q. I'd like to talk about your flagging methodology. And,
7 first of all, you recognize it flags tens of millions of
8 orders, correct?

9 A. Yes.

10 Q. And you have claimed that every one of those tens of
11 millions of orders were likely to be diverted?

12 A. More likely than not, yes, sir.

13 Q. You didn't actually review any of the orders flagged by
14 your methodologies, correct?

15 A. I did not.

16 Q. Not one of the initial orders, correct?

17 A. Well, can I -- clarification of that, I have reviewed
18 them now, but at the time that we last spoke, I did not.

19 Q. Okay. And at the time I had the chance to take your
20 testimony, you did not; correct?

21 A. That's correct.

22 Q. And at the time you sponsored them in your expert
23 report, you did not?

24 A. I did not go back and look at every trigger, that's
25 correct.

1 Q. You didn't look at any of them at the time you wrote
2 your expert report and adopted them; correct?

3 A. That's correct.

4 Q. Not one of the initial orders; not one of the follow-up
5 orders; correct?

6 A. That's correct. I'm sorry. I didn't know that was a
7 question.

8 Q. And you -- as an illustration of that, you haven't
9 looked at which pharmacies generate the most flagged orders
10 under your methodology, correct?

11 A. At the time we talked before, I didn't, we didn't, but
12 I've since went back and reviewed all of the triggers, so --

13 Q. Okay. Do you know which pharmacy triggered the least
14 orders under your method?

15 A. Not as I sit here. I didn't memorize and recite them,
16 but I did look and see which ones triggered and -- how quick
17 they triggered and the amounts they triggered based on our
18 previous conversations.

19 Q. Where did Rite Aids fit in the picture? Were they the
20 most? Were they the least? Were they somewhere in between?

21 COURT REPORTER: I'm sorry. Can you slow down
22 just a little for me?

23 MR. SCHMIDT: Yes. I'm sorry.

24 COURT REPORTER: Were they the most --

25 MR. SCHMIDT: Actually, I'll withdraw the

1 question.

2 BY MR. SCHMIDT:

3 **Q.** None of that is in your report? None of that was in
4 your opinions before the Court today, correct?

5 **A.** That's correct.

6 **Q.** And you performed no analysis in your report or in your
7 opinions today of whether pharmacies that took more or less
8 care to meet their corresponding responsibility had more or
9 less flagged orders, correct?

10 **A.** That's -- I made no correlation between the
11 pharmacists' corresponding responsibility and the flagged
12 orders, Your Honor.

13 **Q.** This is a long one. I apologize for that. I wrote no
14 correlation with corresponding responsibilities. In terms
15 of these orders that you claim were likely diverted, you
16 don't know how many of those orders went to fill legitimate
17 medical need, correct?

18 **A.** I do not, Your Honor.

19 **Q.** You don't know whether it's 99 percent of the flagged
20 orders that went to legitimate medical need, 1 percent, or
21 some other number?

22 **A.** I do not know, Your Honor.

23 **Q.** So, the results of your methodologies are not based on
24 any estimate of medical need, correct?

25 **A.** That's correct. It doesn't include a basis for a -- or

1 a requirement for medical need.

2 **Q.** And I believe you said in your direct examination at
3 one point that 90 percent of the pills should not have been
4 shipped. Do you remember saying something to that effect?

5 **A.** Yes. Based on the assumption, that's correct.

6 **Q.** Now, if that view were followed, how many cancer
7 patients would have been deprived of medication?

8 **A.** Well --

9 **Q.** How many, sir, do you know?

10 **A.** So, what I report to the judge, what I report to you,
11 Your Honor, is -- is more likely than not how many of those
12 pills could have the potential for diversion because the
13 first order didn't have a due diligence inspection or didn't
14 dispel the diversion.

15 It's not saying that none of those 90 percent would
16 actually have been distributed because they actually were
17 when there was no due diligence. What I'm saying is the
18 likeliness of the potential of diversion is based on the
19 fact that that first order wasn't clear and that that
20 suspicion of diversion is present.

21 **MR. SCHMIDT:** Your Honor, may I ask the witness to
22 answer my question now?

23 **THE COURT:** Yeah. Yeah. The question was how
24 many, wasn't it?

25 **BY MR. SCHMIDT:**

1 Q. Yeah. Do you know how many?

2 A. I do not, Your Honor.

3 Q. Do you know how many patients recovering from surgery
4 would be deprived of medication if your opinions were
5 followed?

6 A. I do not.

7 Q. Do you know how many patients receiving end of life
8 care would be deprived of medications if your opinions were
9 followed?

10 A. Your Honor, I do not.

11 Q. Do you know how many doctor prescriptions for
12 legitimate medical need would not be filled if your opinions
13 were followed?

14 A. I do not, Your Honor.

15 Q. And so, I take it you have not done a specific
16 assessment if you haven't looked at the orders and you've
17 not looked at which ones were based on medical need and
18 you've not done an assessment of whether specific flagged
19 orders led to specific harm; true?

20 A. That's a correct statement, Your Honor.

21 Q. So, I'll write not based on harm. Now, I want to get
22 at this point in another way and I think what I'd like to do
23 is if I can show you some of those demonstratives that you
24 looked at with Mr. Farrell.

25 MR. SCHMIDT: Do I need to switch the screen

1 around? This is fraught with possibility for disaster, but
2 okay. Could we put Slide 17 and Slide 18 up next to each
3 other, please?

4 BY MR. SCHMIDT:

5 Q. You talked about having six different methods. This is
6 just two of them, Method A, Method B, and those are going to
7 be the ones I'm going to focus on most of all for reasons
8 we'll talk about.

9 A. Okay.

10 Q. I want to just give two illustrations. You did Method
11 A and Method B for oxycodone for McKesson, correct?

12 A. Yes.

13 Q. And using Method A, you get 87.9 percent. Do you see
14 that?

15 A. Yes.

16 Q. Using Method B, you get 22.2 percent. Do you see that?

17 A. I do.

18 Q. Pretty big difference, right?

19 A. That's a big difference.

20 Q. 87.9 percent is over 400 percent times this estimate of
21 20.2 percent, correct?

22 A. It is.

23 Q. Which of those two is the right number?

24 A. I believe that the larger one is.

25 Q. Okay. We'll talk about the difference between those

1 two in a minute.

2 **A.** Okay.

3 **Q.** Is this wrong, yes or no?

4 **A.** It's not wrong, but what it is, is it reflects allowing
5 shipments to occur without the consideration of due
6 diligence, removing the due diligence and just -- and
7 allowing shipments to occur.

8 **Q.** So, I put 400 percent range across your methodologies
9 just based on that single figure. Now, your methodologies
10 purport to be based -- and I think you said this on one of
11 your slides -- on real world methodologies that different
12 distributors were using, correct?

13 **A.** Yes.

14 **Q.** In truth, none of your methodologies precisely
15 implement any Suspicious Order Monitoring System used in the
16 real world, true?

17 **A.** That's correct, Your Honor, because I was never
18 provided the code. If I would have had the exact code to
19 provide to Mr. McCann, then they would be exactly the same.

20 **Q.** And you will recall that we talked about how Dr.
21 McCann, who did use his code, recalled what you had done and
22 what you had relied on stylized illustrations of what might
23 have been happening in the real world?

24 **A.** I -- I recall that he did use that term, Your Honor.

25 **Q.** And do you recall that you agreed with that as an

1 appropriate term?

2 **A.** I don't recall making a comment on that --

3 **Q.** Okay.

4 **A.** -- at this time. I -- I could have, but I don't
5 recall.

6 **Q.** Let's go to the September 11th, 2020 transcript at
7 123:19 and 120 -- I'm sorry. 124:7 -- 124:1-7.

8 MR. FARRELL: Judge, I believe this is an improper
9 attempt to refreshing the witness's recollection. He should
10 be shown the document.

11 MR. SCHMIDT: Your Honor, it's a prior
12 inconsistent statement. He said he didn't remember
13 endorsing that. Here we say I don't take exception to that
14 statement. It's directly inconsistent to the answer he just
15 gave.

16 THE WITNESS: I acknowledge that.

17 MR. SCHMIDT: Okay. Okay.

18 THE COURT: Well, if --

19 BY MR. SCHMIDT:

20 **Q.** So, let me try it this way. Do you agree with Dr.
21 McCann --

22 MR. SCHMIDT: And was I talking over Your Honor?
23 I'm sorry.

24 THE COURT: Yes. Go ahead.

25 BY MR. SCHMIDT:

1 Q. Do you agree with Dr. McCann that these are stylized
2 illustrations of what's happening in the real world?

3 A. He is the doctor and if that's what he said they are,
4 then I agree with him.

5 Q. I've written stylized illustrations on the board. DEA
6 never used these methodologies that you present in your
7 report, correct?

8 A. Not that I'm aware of, no, sir, Your Honor.

9 Q. And you never used them while you were at DEA, correct?

10 A. I did not, Your Honor.

11 Q. Instead, you created these methodologies for the first
12 time for litigation, correct?

13 A. Yes, sir.

14 Q. Created for litigation on the board. You were
15 initially told that you should come up with five
16 methodologies, correct?

17 A. That's correct.

18 Q. You were told that during a conversation with one of
19 the plaintiffs' counsel, correct?

20 A. That is -- yes, sir.

21 Q. Now, if these methodologies actually did flag orders
22 likely to be diverted, that could be tremendously helpful to
23 the public, correct?

24 A. It could be.

25 Q. Have you, since coming up with these methodologies,

1 gone back to any of your colleagues, your former colleagues
2 at the DEA, and said they should use these methodologies to
3 identify likely diversion in the real world? Have you done
4 that?

5 **A.** I have not done that and I guess in your question, I
6 didn't create these. I tried to use methodologies that were
7 similar to the methodologies that were -- that I -- that I
8 discovered or found while doing this case. So, it wasn't
9 something that I created. Although they're not exactly the
10 same, they're, you know, the best that we could do to
11 recreate those methodologies used by the defendants.

12 **Q.** Have you used these style -- have you taken these
13 stylized illustrations that were created for litigation and
14 tried to publish them so they could be peer-reviewed and
15 available for criticism and use if they were actually
16 valuable?

17 **A.** I have not done that, Your Honor.

18 **Q.** Have you attempted to use these stylized illustrations
19 that you never used at the DEA but that you prepared for
20 litigation in any way outside of testifying in a lawsuit?

21 **A.** I have not.

22 **Q.** Now, you've now been hired by plaintiff lawyers suing
23 on behalf of states, correct?

24 **A.** Yes.

25 **Q.** Cities, correct?

1 **A.** Yes.

2 **Q.** And counties, correct?

3 **A.** That's correct.

4 **Q.** Have you gone to any of your clients and said you
5 should use this to make your registration decisions for
6 pharmacies, or distributors, or your re-registration
7 decisions?

8 **A.** I have not done that, but I have not been asked either,
9 Your Honor. I haven't approached anyone to try to tell them
10 to do that.

11 **Q.** Has anyone in the world that you know of adopted the
12 stylized illustrations that you have presented to the Court
13 in this case?

14 **A.** I have no knowledge that anyone has used these based on
15 my publications in the -- in my report that's now open to
16 the public.

17 **Q.** Okay. So, it's been open to the public and no one has
18 used it, correct?

19 **A.** Not that I'm aware of. I said I'm not aware if anyone
20 has.

21 **Q.** Let's go back to your slide presentation, please, and
22 if we could cull up Page 14 of your slide presentation.
23 This is your list of the six methodologies, correct?

24 **A.** That's correct, Your Honor.

25 **Q.** Let's go through a few of them. Am I correct that when

1 it comes to methodologies, C through F, you have not used
2 those methods?

3 **A.** Well, it wouldn't be up to me to use or not. If -- if
4 you're asking me -- if he's asking me, Your Honor, would I
5 -- if someone was to come to me and say should I use these
6 methodologies, I'm not a DEA person anymore. I would tell
7 them no and I would give them reasons why.

8 **Q.** Let me try it one more time. You would not use methods
9 C through F, correct?

10 **A.** If I owned a company, a distributor, and I was going to
11 design a suspicious order system, that's the basis for your
12 question, that's correct, I would not use those.

13 **Q.** Let's focus on these other two. You say Masters here.
14 Do you see that?

15 **A.** Yes.

16 **Q.** That's a reference to the Masters decision, right?

17 **A.** That's correct.

18 **Q.** You don't say Masters here, correct?

19 **A.** Only probably because it didn't fit on the slide, but
20 it's -- it's also a Masters.

21 **Q.** It's also a Masters? That's where I was going,
22 correct?

23 **A.** Yes. It just treats it different with removing the
24 assumption.

25 **Q.** And you acknowledge that Method A differs from Masters

1 in important regards, correct?

2 **A.** Yes.

3 **Q.** Let's talk about that. And before I do, I'm going to
4 talk about both Method A and Method B. This case is the
5 first of your several cases where you've used these
6 methodologies that you used Method B; is that right?

7 **A.** That's correct.

8 **Q.** And you adopted Method B after we had the chance to
9 critique the way Method A was conducted in your other cases,
10 correct?

11 **A.** That's part of the reason, Your Honor, in depositions,
12 questions in depositions, to take a look at it a different
13 way.

14 **Q.** Okay. Let's talk about that so the Court is on the
15 same page as us. Method A and Method B are the same
16 generally except that Method A uses what you refer to as a
17 due diligence assumption and Method B does not, correct?

18 **A.** That's correct.

19 **Q.** And that's what explains that chasm between the two
20 numbers, 87 percent and 20 percent, right?

21 **A.** Yes. More specifically, A differs from B because B --
22 the assumption in B is, is that a suspicious order is
23 identified but yet, the shipping continues. The only
24 difference is it's fixed after the first triggered threshold
25 and that's done for a different reason.

1 Q. Okay. And I'm going to dig into that but, first, I
2 just want to add to this point we've been discussing.

3 New methodology following criticism. I want to talk
4 about that difference, that due diligence assumption. When
5 Dr. McCann ran Method A for you, the way he ran Method A was
6 by using the assumption that distributors did not conduct
7 any diligence on the first flagged suspicious order,
8 correct?

9 A. That's correct.

10 Q. And so, what that means is anytime a first order gets
11 flagged, everything else gets flagged, correct?

12 A. That's correct for each pharmacy.

13 Q. And you have not looked at those initial orders for
14 McKesson, Cardinal and ABDC that are the initial flagged
15 orders under your Method A, correct?

16 A. Could you -- could you ask that a little further and
17 rephrase it? I'm --

18 Q. Sure. Of course, I can.

19 A. -- not sure I understand.

20 Q. I'll ask it just -- just the way we've talked about it
21 before. Have you looked at those initial orders for
22 McKesson, Cardinal and ABDC that are the initial flagged
23 orders of your Method A?

24 A. I have not, Your Honor.

25 Q. Did you individually review any of them to see if you

1 just looked at the order on its face whether you would
2 consider it to be suspicious?

3 **A.** I did not, Your Honor.

4 **Q.** Did you review the diligence files for every one of
5 these tens of millions of flagged orders?

6 **A.** Some, I would say, yes.

7 **Q.** It wouldn't be possible to review all of them, though,
8 and you did not review all of them, correct?

9 **A.** That's correct. I -- I reviewed the files of the
10 defendants, so if -- and I believe those files were past the
11 trigger date. So, I would have reviewed some of the files.

12 **Q.** Okay. You don't know how many of the orders initially
13 flagged under your methodologies were actually investigated
14 and determined not to be suspicious, correct?

15 **A.** Based on the systemic failure, I guess I couldn't rule
16 out possibility that one of them or two of them were
17 investigated, Your Honor, but just based on my review, there
18 was very little to no due diligence investigations, so I
19 would say I wouldn't have to review that to have an opinion
20 on that.

21 **Q.** Can we cull up the September 11th, 2020 transcript at
22 Page 99, Lines 9-17? And do you see I asked you, do you
23 know of those initial flagged orders under Method A how many
24 between 0 and 100 percent were actually investigated and the
25 flag cleared by the defendants? Answer, I don't have a

1 definitive answer to that, sir. Okay. That's not something
2 you tried to evaluate, correct? Answer, I did not. Did I
3 read that correctly?

4 **A.** You did.

5 **Q.** Were you being truthful in giving that testimony?

6 **A.** I was.

7 **Q.** And, in fact, you don't have a number as to how many of
8 these tens of millions of orders should have been reported
9 to the DEA as suspicious, correct?

10 **A.** Well, in Methodology A, if the due diligence is not --
11 the -- the suspicion is not dispelled, there's no due
12 diligence, then every order after that first order.

13 **Q.** Can we look at the September 11th, 2020 transcript at
14 Page 102, please, on Line 20-23? Do you see where I asked
15 you how many of these tens of millions of orders should have
16 been reported to the DEA as suspicious? Do you see that?

17 **A.** I do. And I believe that's a different question than
18 you asked me.

19 **Q.** Okay. What's the answer to how many of these -- the
20 record will say what it says. Let me finish my impeachment
21 and then we can move on. The answer is, I don't have a
22 number, sir. Do you see that?

23 **A.** I would agree with that statement.

24 **Q.** So, in case we misunderstood each other, let me just
25 ask you. Do you know how many of these tens of millions of

1 orders should have been reported to the DEA as suspicious?

2 **A.** No, I do not.

3 **Q.** For shorthand, I'm going to write don't know how many
4 reportable.

5 So, let's go back to this -- this difference between
6 Method A and Method B and I want to illustrate for the
7 Court, if I could, how it works --

8 **A.** Sure.

9 **Q.** -- in terms of that initial order gets flagged and
10 everything after gets flagged, okay?

11 **A.** Sure.

12 **Q.** And do you recall that in his report, Dr. McCann gives
13 an illustration, and I just don't remember if you copied it
14 into your report, but he gives an illustration of a pharmacy
15 where, in a six-month period, you had 5,000, and then
16 10,000, and then 7,000, and 8,000, and 9,000, and 9,500
17 pills. Do you remember that illustration? I can show it to
18 you, if you would like.

19 **A.** I generally recall it. I do not believe it's in my
20 report.

21 MR. SCHMIDT: Okay. So, let's -- if we could put
22 up McKesson Demonstrative 2, please, just for illustration.
23 Do I need to switch the screen?

24 So, we have tried to replicate that example. It's
25 probably going to be covered by that offense. There we go.

1 And could you show us the first illustration?

2 BY MR. SCHMIDT:

3 Q. You'll see I've taken year one, just that illustration
4 I gave you. I moved the months because, for some reason,
5 Dr. McCann started in February and, for ease, I started in
6 January. 5,000, 10,000, 7,000, 8,000, 9,000, 9,500. Do you
7 see that?

8 A. I do.

9 Q. Under your Method A and under your Method B, anytime an
10 order goes over the highest of these first sixth months, it
11 flags it, right?

12 A. That's correct.

13 Q. So, any order over 10,000 flags, correct?

14 A. That's a correct statement, Your Honor.

15 Q. Okay. So, let's fill in the next six months, please.
16 What we filled in for the next six months, you'll see these
17 months, the last four months, repeat the exact same numbers
18 as the first six months. Do you see that pattern?

19 A. I do.

20 Q. And what we did in the first six months and the second
21 six months is they were at a hundred pills less in July and
22 a hundred pills more in August. Do you see that?

23 A. I do.

24 Q. And under your method, because those hundred pills
25 shift -- shifted from July to August, that would flag,

1 right?

2 **A.** That's correct.

3 MR. SCHMIDT: And can we highlight that?

4 BY MR. SCHMIDT:

5 **Q.** Now, the next thing we've done, if we click again, is
6 you know many of these pharmacies have multi-year
7 relationships with the distributors, correct?

8 **A.** Yes, sir.

9 **Q.** So, what I have done here is I've replicated that
10 pattern from the first six months for the entire 12-year
11 period shown here. Do you see that?

12 **A.** Is -- is this a demonstrative or --

13 **Q.** This is a demonstrative, yes.

14 **A.** Okay.

15 **Q.** I'm trying to illustrate how your methodology works.

16 **A.** I understand.

17 **Q.** And the only month that is flagged is this one month
18 where, instead of ordering that hundred pills in July, they
19 ordered them in August. Do you see that?

20 **A.** I do.

21 **Q.** Under your methodology, with that alone, every single
22 one of these orders after this would flag, correct?

23 **A.** That's correct.

24 **Q.** And that's true even though every single one of them
25 follows the exact pattern of the first six months, correct?

1 **A.** That's correct.

2 **Q.** And it would be correct that they would all flag even
3 if, instead of following the pattern of the first six months
4 again and again, every month was actually below the amount
5 of the first six months? They would still flag, right?

6 **A.** That's correct. And that occurs, Your Honor, because
7 when that -- that trigger, no matter the amount, 100, 500 or
8 1,000, the maintenance of effective controls to prevent
9 diversion requires that the registrant take some action and
10 has to do some due diligence.

11 I'm not saying that I or the DEA would close them down
12 for that 100 pills, but they just need to do something to
13 confirm. It's -- the theory here is that it's their system
14 and that's how they designed it and a hundred triggered it.
15 I watched the testimony, I think, of Mr. Mone and he said
16 the exact same thing.

17 MR. SCHMIDT: Your Honor, I don't think he's in a
18 position to comment on other witnesses' testimony,
19 particularly when it goes well beyond anything I asked him.

20 THE COURT: Well, I think that's right.

21 MR. FARRELL: Judge, I respectfully disagree.
22 He's explaining his answer.

23 MR. SCHMIDT: I won't make Cardinal's objections
24 for them. I suspect he's misconstruing Mr. Mone's
25 testimony, but I don't think, in any event, it's his place

1 to comment on a witness's testimony when my simple question
2 was how does this work.

3 MR. FARRELL: So, he asked how it works and the
4 witness is trying to explain it.

5 MR. SCHMIDT: My question was simply would it
6 flag.

7 THE COURT: Well, I'll sustain the objection to
8 the reference to Mone's testimony. That -- that's what
9 you're objecting to, isn't it?

10 MR. SCHMIDT: Yes.

11 MR. FARRELL: I believe it was Mr. Smith's motion
12 to strike.

13 MR. SCHMIDT: Yes.

14 MR. FARRELL: I certainly didn't object to the
15 reference to Mr. Mone.

16 MR. SCHMIDT: May I continue, Your Honor?

17 THE COURT: Yes.

18 MR. SCHMIDT: Okay.

19 BY MR. SCHMIDT:

20 **Q.** Every -- if every month from year 2 to year 12 was a
21 hundred pills, every one of those months would still flag;
22 true or not true?

23 **A.** That's a true statement, Your Honor, if that first
24 order didn't have the -- the due diligence didn't clear the
25 suspicion.

1 **Q.** Thank you. Now, the due diligence assumption that
2 we've been talking about here in your Method A was not used
3 in the Masters program in the real world, correct?

4 **A.** Well, I think not the exact methodology, but I think
5 that application that in the Masters case the problem was,
6 is that Masters didn't do the proper due diligence and
7 continued to ship suspicious orders, which is similar to how
8 it's applied here. So, I don't totally agree with that
9 statement that you made.

10 **Q.** Okay. Could we cull up the September 11th, 2020
11 transcript by video at 137:21-24.

12 (Recording played in open court)

13 BY MR. SCHMIDT:

14 **Q.** Were you being truthful when you gave that horrible
15 looking testimony for both of us over Zoom?

16 **A.** That's what I said at that time.

17 **Q.** Okay.

18 **A.** I'm not sure the questions were exactly the same, but
19 that was my answer.

20 **Q.** Well, we have the record for that, thankfully.

21 **A.** Okay.

22 **Q.** If a distributor identifies -- let me ask you a very
23 precise yes or no question, if I may, Mr. Rafalski.

24 **A.** If I can answer it, Your Honor.

25 **Q.** If a customer identifies a suspicious order, does that

1 require the suspension of all orders or sales of other
2 controlled substances to that customer?

3 **A.** If the question is all, the answer would be no.

4 **Q.** And, in fact, you testified to that very point when you
5 were a government official, didn't you?

6 **A.** Yes.

7 **Q.** You're not aware of any company or regulator who has
8 ever run Masters Exhibit A with a due diligence assumption
9 to any set of data at any point in time, correct?

10 **A.** That's a correct estimate, Your Honor. I'm not aware
11 if someone did not.

12 **Q.** There's no general acceptance you can point me to for
13 Method A with its due diligence assumption, whether it's by
14 distributors, regulators or academics, correct?

15 **A.** That is a correct statement, Your Honor.

16 **Q.** The DEA has never conducted this exercise of applying
17 your Method A to identify diversion, correct?

18 **A.** That's a correct statement, Your Honor.

19 **Q.** In fact, you've told me it wouldn't be a valid exercise
20 for the DEA to attempt to use your Masters A to identify
21 diversion, correct?

22 **A.** And apply the assumption, that would be a correct
23 statement. I believe I testified before that if, after the
24 ruling by the DC appellate court, I may be tempted to use
25 the Masters six-month evaluation if I was still working. I

1 think the ruling there kind of validated it.

2 **Q.** So, let's -- let's go back to how you came up with
3 Method B and this idea of it being a new methodology
4 following criticism.

5 **A.** I don't agree with that statement.

6 **Q.** Okay. Well, let's talk about it.

7 **A.** Okay.

8 **Q.** Was Method B a new methodology?

9 **A.** It was.

10 **Q.** Was it a new methodology in this case after you had
11 failed to use it in two other cases?

12 **A.** It was.

13 **Q.** Was it a new methodology following criticism we offered
14 of Method A, including on just the very points we've
15 discussed today in earlier depositions?

16 **A.** There was criticism, but I didn't run it specifically
17 because of the criticism. I wanted to run it to see how
18 different it would turn out.

19 **Q.** Okay. My question is simply a temporal question. You
20 had Method A. We had the chance to take issue with it.
21 Point out issues with it. Point out that it wasn't actually
22 Masters in terms of the due diligence assumption. And then,
23 for the first time in this case, after two prior reports,
24 you got Method B, correct?

25 **A.** That's correct. I wanted to see what the results would

1 be to remove the assumption.

2 **Q.** And the results show that your flagging drops by more
3 than a quarter when you remove that assumption, correct?

4 **A.** It does.

5 **Q.** Now, we have since been able to depose you regarding
6 your Method B, correct?

7 **A.** Yes.

8 MR. SCHMIDT: And can we actually go back to I --
9 believe it's slide 14 from the demonstrative deck? It's the
10 one -- yeah, that's the one. Thank you. Put it back on the
11 screen.

12 BY MR. SCHMIDT:

13 **Q.** One of the issues that we had the chance to discuss
14 with you regarding Method B, which you've told us is
15 supposed to be based on Masters, right?

16 **A.** It's similar.

17 **Q.** Okay.

18 **A.** Yes.

19 **Q.** One difference between Method B and Masters is the way
20 they calculate the calendar months, correct?

21 **A.** That's correct.

22 **Q.** And we had the chance to ask you about that concern
23 with Method B in your deposition in this case, correct?

24 **A.** That's correct.

25 **Q.** And following that, you've come up with yet another

1 method in another new case not before this Court that
2 doesn't appear on this screen, correct?

3 **A.** Yes.

4 **Q.** Are we done with your methods or will you continue to
5 refine your methods?

6 MR. FARRELL: Objection, Your Honor,
7 argumentative.

8 THE COURT: Overruled.

9 THE WITNESS: I think -- I don't think anything is
10 etched in stone, Your Honor. I think what I'm trying to do
11 is present something for you to be able to -- to evaluate
12 and make a decision on. I think there's a limit to how many
13 different methodologies you'd do. I'm -- you know, I use
14 the ones that are up there now, and then still continue to
15 use the Masters. Only the one that we're speaking about now
16 goes to the 30-day instead of the month. And because those
17 were just identified in this litigation to just arbitrarily
18 make one up, I don't think would be fair either, but I -- I
19 just want to present some facts and information to the Court
20 and that's the purpose of this.

21 **Q.** So, let me just try to close out that question, Mr.
22 Rafalski. You know we have a deposition coming up next week
23 in another one of your cases, correct?

24 **A.** Yes.

25 **Q.** And then, you've got that pharmacy deposition I've

1 mentioned a few times in a couple of weeks, correct?

2 **A.** Yes.

3 **Q.** And I trust you expect we might come up with new
4 critiques of some of these methods in those depositions as
5 we've done previously, correct?

6 **A.** I fully expect it, Mr. Schmidt.

7 **Q.** We try to do our job and we'll try not to disappoint
8 you. I -- my question is --

9 **A.** I'm not looking forward to it, just for clarification,
10 Your Honor.

11 **Q.** Well, we've been here four weeks. I'm not looking
12 forward to it either, for what it's worth.

13 My question to you simply is can you rule out the
14 possibility that following those critiques you'll come up
15 with another method?

16 **A.** I think I might have run out of methodologies used by
17 the defendants, so I think that's a good possibility. I
18 don't think any of the other ones could be modified in a way
19 that Masters would be, so --

20 **Q.** Do you know what -- go ahead. I'm sorry.

21 **A.** So, I would probably say I don't think there would be
22 any further methodologies, but I wouldn't rule that out if I
23 thought something could, you know, provide another
24 opportunity for the Court to look at, the use of a
25 methodology and the results of it.

1 **Q.** And if we did this new Method G that you've done in the
2 pharmacy case but not here, do you know precisely what it
3 would show for these three defendants?

4 **A.** I do not know precisely.

5 **Q.** Okay. I want to go back to the white board, if I
6 could, and I'd like to ask you about one more point
7 regarding your flagging methodologies.

8 Am I correct that the way your Method B works is that
9 the threshold under Method B never changes based on any
10 subsequent development?

11 **A.** That's a correct assumption, Mr. Schmidt -- or Your
12 Honor.

13 **Q.** I've written never changes based on development. Do
14 you see that?

15 **A.** I do see that. There's a reason for that, if I could
16 explain it to you.

17 **Q.** And it doesn't change to account for population shifts,
18 correct?

19 **A.** That's correct.

20 **Q.** It doesn't change to account for demographic changes,
21 correct?

22 **A.** That's a correct statement, Your Honor.

23 **Q.** And it doesn't change to account for shifts in medical
24 needs in Cabell County, correct?

25 **A.** That's correct, too.

1 **Q.** And you can't point me to any generally accepted
2 methodology for identifying and reporting suspicious orders
3 that ignores entirely what the medical community is doing in
4 terms of increased legitimate prescriptions, true?

5 **A.** That's a correct statement.

6 **Q.** Okay. Are you -- are you aware that doctors in
7 Huntington and Cabell County were making the decision to
8 prescribe more and more? I'm going to write doctors on
9 here. More and more prescription opioids?

10 **A.** Yes. The charts that were used today would indicate
11 that.

12 **Q.** How would they indicate that?

13 **A.** Well, the more drugs that are being dispensed are
14 pursuant to a prescription.

15 **Q.** You get the prescription, that goes up, and then the
16 distribution goes up, correct?

17 **A.** That's correct. No other way for those charts to
18 increase without prescriptions.

19 **Q.** No other way, right?

20 **A.** That's correct.

21 **Q.** Okay. And so -- I apologize. I don't think I asked
22 this, but let me be sure I did. Method B does not adjust
23 threshold levels at all based on whether doctors are making
24 the judgment to legitimately prescribe more or less
25 prescription opioids, correct?

1 **A.** That's correct, Your Honor. The reason why that
2 threshold is fixed, it also applies an assumption, a due
3 diligence assumption, in a different way.

4 If I was allowed, running that methodology, for the
5 threshold to change, then it means that I'd be accepting
6 potentially diverted orders. If they were escalating and
7 it's fixed because of that purpose, that would be similar to
8 something I did if I was working.

9 Because when you're trying to evaluate some of the
10 cases I worked on, you wouldn't allow the potential diverted
11 months to be included in adjusting the threshold and it
12 wouldn't be accurate. So, that's the reason why it was
13 fixed.

14 MR. SCHMIDT: Can we go back to the slides that
15 were used with Mr. Rafalski? And if we could look at Slide
16 15, please.

17 BY MR. SCHMIDT:

18 **Q.** Do you remember talking with Mr. Farrell about this
19 slide, sir?

20 **A.** I do.

21 **Q.** And the idea in this slide is every month the level of
22 distribution is increasing?

23 **A.** That examples, yes, sir.

24 **Q.** Okay. And when I looked at this slide, it looked
25 almost exactly like the level of prescribing that increased

1 month by month in Cabell and Huntington. Do you know
2 whether this example you gave directly tracks what happened
3 in the real world in terms of prescribing in Huntington and
4 Cabell?

5 **A.** That was just a demonstrative and I didn't try to copy
6 or recreate any particular graph or exhibit.

7 **Q.** Understood. Understood. But you know generally that
8 prescribing in Huntington and Cabell for a multi-year
9 period, up until about 2012, in that window, increased just
10 like that?

11 **A.** I don't disagree with that, Your Honor. I would
12 probably say that most places in America probably increased
13 like that.

14 **Q.** And excuse me. I'm sorry. If I tracked your
15 walkthrough of these different methods with Mr. Farrell,
16 under any of the methods, if you have that prescribing
17 increasing, even if it's for legitimate medical reasons, all
18 your methods will flag it at some point, right?

19 **A.** If there's no due diligence done and to clear that
20 order or an evaluation by a distributor to raise or change
21 the threshold, if it's a legitimate use, then that's a
22 correct statement.

23 **Q.** Well, Dr. McCann didn't review due diligence files, did
24 he?

25 **A.** He did not.

1 **Q.** He just applied these methods with assumptions,
2 correct?

3 **A.** Yes, my assumption, that's correct.

4 **Q.** And so, to ask my question, just by normal growth in
5 prescriptions, you're going to be flagging a large number of
6 orders under every one of your methods, correct?

7 **A.** If they grow in that manner, then that's correct, yes,
8 Your Honor.

9 **Q.** All right. Let me give you a different example. Your
10 Method B -- and all your methods don't change even if the
11 DEA raises its quota, do they?

12 **A.** They do not.

13 **Q.** And you remember, I'm not going to go back through it,
14 but the DEA quota was constantly changing up until about
15 2013, correct?

16 **A.** That's an accurate statement, Your Honor.

17 **Q.** Is there anytime you know of where, when you were at
18 the DEA, you told distributors you should pick six months of
19 data as you do in Method B and never adjust your thresholds
20 even if the DEA quota is going up? Did you ever tell
21 distributors that?

22 **A.** No. I wouldn't make -- first of all, as -- my agency
23 restricts me from giving opinions or recommending systems to
24 a registrant, but, you know, the basis for this is the due
25 diligence issue and whether or not it's conducted. I

1 understand what you're asking, but I wouldn't have ever went
2 to any registrant and advised them on any system.

3 **Q.** Did you ever try to identify distributors who you
4 believed were improper, acting improperly, because even
5 though their levels were rising in connection with the
6 quota, they quickly started exceeding the first six months?
7 Did you ever take action against the distributor on that
8 basis while at DEA?

9 **A.** Well, it would be Masters, but I don't know if it was
10 the first six months.

11 **Q.** Okay. Now, let me ask you this question. If -- and
12 this goes back to my question about whether you might have a
13 new method down the road.

14 MR. SCHMIDT: Can we go to Slide 14, please?

15 BY MR. SCHMIDT:

16 **Q.** This is the slide with your six methods. And if we
17 could add that Method G from the other case that doesn't
18 appear in this case.

19 If you took any one of your methods, let's say Method
20 B, and then -- let me pause for a second.

21 Method B works in a similar way to Method A where you
22 look at the first six months of data, correct?

23 **A.** Yes, sir.

24 **Q.** And the highest number in that first six months
25 controls, correct?

1 **A.** Sets the threshold for the next month.

2 **Q.** Right. But you can never go above that highest number,
3 right? Anytime you go above that highest number, you're
4 going to trigger, right?

5 **A.** That's correct.

6 **Q.** Okay. So, have you ever tried to do a method where you
7 take something like that, look at the first six months of
8 data, and then for the next six months, instead of basing it
9 just on the highest month, you base it on the highest month
10 adjusted for how many more prescription opioids doctors are
11 writing?

12 **A.** I have not.

13 **Q.** Have you ever tried to conduct an analysis like that
14 where instead of just fixing it at the amount of the first
15 sixth months, that you take that number and adjust it based
16 on how much the quota is going up?

17 **A.** I have not, Your Honor, and that's not the purpose for
18 this methodology to provide to you, but I have not done
19 that.

20 **Q.** Do you know how many flagged orders you would generate
21 if you did take changes in prescribing or changes in the
22 quota and used them to adjust your maximum?

23 **A.** No, I do not.

24 **Q.** Do you know if you would flag any orders with
25 specificity?

1 **A.** So that -- so I understand the question, the question B
2 is if I somehow used a methodology to incorporate the
3 increase in the quota?

4 **Q.** Or prescribing levels?

5 **A.** Or prescribing levels?

6 **Q.** Do you know if you flag any orders?

7 **A.** I think you still would.

8 **Q.** Do you know how many it would be?

9 **A.** I don't -- no, I do not but just, you know, the
10 diversion and how it occurs is unusual increases. And so, I
11 believe that you would flag orders.

12 **Q.** Okay. Do you know if it would go from 80 to 20 to
13 something far south of 20 or if it would be different?

14 **A.** I don't have any idea.

15 **Q.** Okay.

16 **A.** I believe it would be less than 80.

17 **Q.** Okay. Are you aware that the DEA has actually used
18 techniques to try to estimate the amount of diversion and
19 has produced estimates of the amount of diversion over the
20 past two years?

21 **A.** The only one I'm aware of is in the -- this recent
22 Federal Register publication.

23 **Q.** Okay. That's the Support Act, correct?

24 **A.** Yes.

25 **Q.** And specifically what Congress did through the Support

1 Act is it charged the DEA with trying to come up with
2 estimates of diversion in the context of setting its quota,
3 right?

4 **A.** Just so we're talking about the same Federal Register,
5 I'm talking about the proposed rules for the suspicious
6 orders system.

7 **Q.** Okay. I'm talking about something different.

8 **A.** The one we had talked about previously?

9 **Q.** Yes, sir.

10 **A.** Okay.

11 **Q.** So, now that we're re-oriented, let me try my question
12 again and see if you agree with me. Are you aware that
13 through a law called the Support Act Congress has charged
14 the DEA with coming up with estimates of how much diversion
15 is occurring to inform their decisions about quota setting?

16 **A.** Yes. I recall us discussing that previously.

17 **Q.** And that is something that -- they're charged with
18 trying to come up their best methodology to estimate levels
19 of diversion, correct?

20 **A.** Yes. And I recall, if we're talking about the same
21 one, there's a little criticism about the DEA being kind of
22 incomplete in their gathering of information to make that
23 estimation, if that's the correct one we're speaking about.

24 **Q.** That's required by law, right?

25 **A.** Yes.

1 Q. And it's only been for the past couple of years,
2 correct?

3 A. I believe I've only read one report based on that law.

4 Q. And you recall that we've had the chance to do math
5 together on that and calculate that for the past couple
6 years for oxycodone and hydrocodone and the DEA's
7 calculations are less than .1 percent diversion using their
8 method, correct?

9 A. Yes. And I believe that I didn't agree with that.

10 Q. You've done the type of calculation of actual diversion
11 that the DEA has conducted, correct?

12 A. I have not. I just draw -- I make that statement just
13 based on the pure number.

14 Q. You've never published your estimates, your flagging
15 methods, with a source like the Federal Register as you know
16 the DEA has?

17 A. I have not, Your Honor.

18 Q. And you're not aware of anyone who has tried to conduct
19 the same types of calculations of actual diversion that the
20 DEA has conducted, which show less than .1 percent diversion
21 and come up with different numbers, are you?

22 A. I am not.

23 Q. Okay. I'm going to change gears now and this will
24 probably take us through the day. Starting in 2007 and
25 2008, are you aware that McKesson, ABDC and Cardinal began

1 automatically blocking orders that exceed thresholds?

2 **A.** I am. All of them develop new programs in that time
3 frame and all of them included a block of orders.

4 **Q.** You can't point me to any company before 2007 that
5 blocked every order that went over a threshold or that it
6 reported to the DEA, correct?

7 **A.** As I sit here, I'm not aware of one, but I can't say
8 that one didn't exist, Your Honor.

9 **Q.** And do you know of a prior public occasion when the DEA
10 said any order you identify as suspicious should not be
11 shipped prior to this 2007 window we're talking about?

12 **A.** In those exact terms, Your Honor, that's -- I do not
13 know of that.

14 **Q.** DEA never specifically told McKesson, ABDC or Cardinal
15 not to ship an order identified as suspicious before that
16 time period, correct?

17 **A.** Not in those exact terms, although I think there's been
18 discussions where they talk about the maintenance of
19 effective controls to prevent diversion, and they talk about
20 identifying a suspicious order, and they talk about
21 companies having a liability or a responsibility for public
22 interest. So, I think if you put that together, it says
23 that, but to actually -- if I understand the correction to
24 say do not ship, no, I am not aware that they've said that
25 in that way.

1 **Q.** Before 2007, DEA never took action against the company
2 because they reported orders, but did not block them,
3 correct?

4 **A.** I don't want to split hairs. Southwood might have been
5 in 2006, but --

6 **Q.** Southwood was 2007, sir. If you want to look back at
7 your slide with it on it, I can refresh you. Why don't we
8 put that up?

9 **A.** I think that may be the ruling, but I think the action
10 -- action might have been sooner, but I'm not disputing the
11 2007.

12 **Q.** Okay.

13 **A.** I don't want to argue about a year.

14 **Q.** And you, yourself, acknowledged that there was no do
15 not ship requirement before 2007 when you were a DEA agent,
16 correct?

17 **A.** I -- I recall that I was testifying. We've discussed
18 it before and I was asked and I believe I said it was a
19 change in policy.

20 **Q.** In this 2007 time frame, correct?

21 **A.** I don't remember the exact time frame. I think it was
22 just in reference to -- I don't remember if I testified in
23 reference to the distributor briefings or the Rannazzisi
24 letters.

25 **Q.** Okay. Those all happened in the 2006-2007 time frame,

1 correct?

2 **A.** Well, the distributor briefings were in '05.

3 **Q.** They started in early January 2006 and went into 2007
4 according to your testimony, correct?

5 **A.** The distributor briefings?

6 **Q.** The distributor initiative?

7 **A.** I believe they occurred for the defendants in '5 and
8 '6.

9 **Q.** Okay. Well, whatever year we're talking about in that
10 window, you testified that before that time the DEA never
11 told distributors not to ship orders they were reporting,
12 correct?

13 **A.** I don't know if I testified to those exact words. I do
14 recall that, when questioned about it, I said it was a
15 change in policy and that was based on some information that
16 was provided me by another diversion investigator.

17 **Q.** Okay. Let me ask you about the context where this
18 testimony came up. You were involved in a case called
19 *United States v. \$463,497.72*. Do you remember that?

20 **A.** Yes, sir.

21 **Q.** You were actually the chief investigator in that case,
22 correct?

23 **A.** I was.

24 **Q.** And you were deposed in that case?

25 **A.** That's where I made the statement, sir.

1 **Q.** And you testified at trial in that case?

2 **A.** I didn't testify to that at trial, but I did at the
3 deposition, yes, sir.

4 **Q.** In that case, you testified that distributors were
5 first told about the do not ship requirement as part of the
6 distributor initiative, correct?

7 **A.** I believe -- I believe that's a true statement. I
8 think that that's the first time the DEA made a more
9 definitive statement do not ship.

10 **Q.** And you said -- I'm sorry.

11 **A.** No, go ahead.

12 **Q.** You said those distributors briefings began in January,
13 2006, correct?

14 **A.** If that's what I testified to, looking at -- now
15 looking at some of the distributor briefings as part of my
16 review of records in this case, I see that they were in
17 2005.

18 **Q.** And that's since you've been hired as a plaintiffs
19 expert and given documents by plaintiffs' attorneys,
20 correct? True?

21 **A.** Well, yes, looking at discovery material, that's
22 correct.

23 **Q.** I want to focus on what you were doing when you were
24 severing the United States Government as a diversion
25 investigator. At that time, you said distributor briefing

1 started in January, 2006, correct?

2 **A.** If I made that statement, then that's what I believed
3 at that time and it would have been provided to me by
4 another diversion investigator, not actually looking at the
5 documents of the briefing.

6 **Q.** And you testified that the do not ship requirement is
7 not contained in the regulations or the statutes, correct?

8 **A.** The actual words do not ship do not appear anywhere in
9 the statute or in the regulations.

10 **Q.** And you said that they were only informed of it by the
11 DEA in these distributor briefings, correct?

12 **A.** I was aware they were informed of it then, yes, sir.

13 **Q.** There was a published court decision based on your
14 testimony, correct?

15 **A.** Yes, there was, Your Honor.

16 **Q.** And you read that decision when it came out?

17 **A.** I did.

18 **Q.** You testified in that case, before the judge in that
19 case?

20 **A.** I did, Your Honor.

21 **Q.** And your colleagues testified in that case, before the
22 judge in that case?

23 **A.** Yes, other diversion investigators, if you mean that,
24 yes, sir.

25 **Q.** That is what I mean, sir.

1 **A.** Yes, sir.

2 **Q.** You had the chance to sit there and hear them testify?

3 **A.** I did sit there. I was the officer in charge of the
4 investigation, Your Honor. I watched all their testimony.

5 **Q.** Because you were the chief investigator in this case,
6 correct?

7 **A.** I was.

8 **Q.** Do you recognize what I've marked as DEF-WV-2661 as the
9 case where you testified and where you were, in fact, the
10 chief investigator?

11 **A.** I do recognize this, Your Honor.

12 MR. SCHMIDT: Your Honor, again, we don't think
13 it's appropriate to move a case into evidence, but I do
14 think it's relevant, and the Court can take judicial notice
15 of it. So, absent objection, I will put it up on the
16 screen.

17 THE COURT: All right.

18 MR. SCHMIDT: Let's go to Page 5 of this decision.
19 And can we cull out the first paragraph under (f)? It
20 states -- the second sentence there states the regulations
21 do not prescribe any particular form or style of monitoring
22 system. Do you see that?

23 **A.** I do see it and I believe that's an accurate statement.

24 **Q.** Got me on my next question. Thank you. Let's go to
25 Page 6, please, and if we could cull out the third and the

1 fourth paragraphs, please.

2 And let's start with the first -- I'm sorry. Let's
3 start with the second sentence. The government offered
4 testimony that the DEA sought to expand drug wholesalers'
5 obligations by a policy change in 2006 and 2007, although
6 there was never a change to the regulations. Do you see
7 that?

8 **A.** I do.

9 **Q.** That's consistent with the testimony you gave in that
10 case, correct?

11 **A.** I didn't give testimony in regards to that in the
12 federal trial. That was -- I think we were discussing my
13 deposition testimony.

14 **Q.** That's consistent with deposition testimony you gave in
15 that case, right?

16 **A.** I did make that statement in the deposition, yes, only
17 in regards to a change in policy.

18 **Q.** There was never a change to the regulation; that's
19 true, right?

20 **A.** Yes.

21 **Q.** One of the changes in interpretation by the DEA
22 concerned the circumstances under which a distributor should
23 suspend shipments to a customer if it identified an order as
24 suspicious. Do you see that?

25 **A.** I do.

1 Q. And do you know that they're talking about the do not
2 ship requirement there?

3 A. I believe that's what they're referring to.

4 Q. And they say that change in policy apparently prompted
5 concern within the DEA compliance sectors that confusion
6 would result since the prior report only, that's the
7 opposite of blocking, right? Yes?

8 A. Yes. Yes. I'm sorry. I didn't know you were done. I
9 didn't know you were done speaking. I'm sorry.

10 Q. That change in policy apparently prompted concern
11 within the DEA compliance sectors that confusion would
12 result since the prior report-only policy had been in place
13 for 35 years. Do you see that?

14 A. That's what this says, yes, sir.

15 Q. Therefore, DEA personnel began to conduct distributor
16 briefings to familiarize drug wholesalers with the new
17 policy. Do you see that?

18 A. That's what it says, Your Honor.

19 Q. And that's the distributor briefings we've been talking
20 about in '06 and '07, correct?

21 A. Yes, it is.

22 Q. And then there's reference to Kyle Wright conducting
23 one of those distributor briefings, correct?

24 A. That's correct.

25 Q. And I think you might have been involved in some later,

1 but you were not involved in any during that time period,
2 correct?

3 **A.** I went and actually watched a distributor briefing.
4 Didn't participate other than to observe it in the Fall of
5 2008.

6 **Q.** And then, let's look down in the next paragraph. In
7 all events, Wright -- that's a reference to Kyle Wright, one
8 of your colleagues at DEA, right?

9 **A.** Yes.

10 **Q.** Wright testified that the DEA was aware that it was
11 standard practice in the industry to file Suspicious Order
12 Reports while continuing to ship products. Do you see that?

13 **A.** I see that.

14 **Q.** And you are aware that Agent Wright gave that
15 testimony, right? You watched him give it?

16 **A.** I'm aware of it, Your Honor.

17 **Q.** It goes on to say and that practice had been approved
18 by the DEA. You're aware he gave that testimony, correct?

19 **A.** I'm aware he did.

20 **Q.** You watched him give it, correct?

21 **A.** I did.

22 **Q.** And as the chief investigator on this case, you never
23 stood up to disagree with him, correct?

24 **A.** I did not.

25 **Q.** Let's go to Page 6, please, of the opinion. I guess

1 we're actually on Page 6, further down, second paragraph
2 from the bottom. Mentions another one of your colleagues in
3 this second sentence. Do you know who Michael Mapes is?

4 **A.** I do.

5 **Q.** Also one of your colleagues at DEA?

6 **A.** He was also employed at the DEA. I guess he would be a
7 colleague. To me, that infers there's some kind of like a
8 personal relationship versus just another employee, but
9 either way.

10 **Q.** One of your fellow agents at DEA?

11 **A.** Yes, investigators, that's correct.

12 **Q.** Fellow investigators. This says Wright's supervisor,
13 Michael Mapes, told distributors at the DEA's Pharmaceutical
14 Industry Conference on September 11th, 2007 that the DEA's
15 new interpretation of the suspicious order regulation was
16 that the distributors should suspend shipments if they
17 routinely report suspicious orders with no reason to -- with
18 reason to believe they are destined for the illicit market.
19 Mapes informed Wright of that policy interpretation as well.
20 Do you see that?

21 **A.** I do.

22 **Q.** Did you take any issue with that testimony when you
23 were there?

24 **A.** I didn't at that time. I don't agree with it now.

25 **Q.** Well, do you have any facts that let you say

1 characterizing this as a new interpretation of a suspicious
2 order regulation is wrong?

3 **A.** Well, in looking back now at getting -- you know,
4 looking at some of the information in some of the exhibits
5 or some of the information in reviewing, I see comments by
6 the DEA back as far as 1987. There was a -- Ron Buzzeo had
7 a seminar and there was -- there was a report or a summation
8 of what happened in his report. And one of the questions
9 asked if there was one of the -- he said it was an active
10 discussion which, to me, meant that it was not heated, but
11 active, and one of the registrants asked if we ship -- if we
12 ship and then report, can the DEA take action and his
13 comment back was, and I think I've talked about it earlier,
14 is to do that is a registrant's not taking the public safety
15 in effect. Indirectly, I think that's what he's saying, but
16 it wasn't as clear as saying hold here and do not ship.

17 **Q.** Can we cull up the September 11th, 2020 testimony at
18 219:10-13? Do you see where you were asked last September
19 the same question I just read to you, do you have any facts
20 that let you say characterizing this as a new interpretation
21 of the suspicious order regulation is wrong? Your answer, I
22 do not. Did I read that correctly?

23 **A.** You did.

24 **Q.** Were you testifying truthfully at that time?

25 **A.** I was.

1 Q. Okay. Let's look at another part of the opinion.

2 Actually, could we go back to where we were?

3 A. Which -- which -- can I ask a question? When was this
4 deposition?

5 Q. September 11th, 2020.

6 A. Okay, thank you.

7 Q. After you've given your report in this case, correct?

8 A. Yes.

9 Q. After you've given your report in New York, correct?

10 A. Yes, only --

11 Q. After you've given your report in Cuyahoga County,
12 correct?

13 A. That's correct. Only I -- I'd like to read more of the
14 deposition. I'm sorry.

15 MR. IRPINO: Your Honor, could he let him finish?

16 THE COURT: Yes. Let him finish his answer, Mr.

17 --

18 MR. SCHMIDT: I'm going to object to multiple
19 objectors.

20 COURT REPORTER: I'm sorry. What was your name?

21 MR. IRPINO: Anthony Irpino.

22 THE COURT: Overrule that objection. You go
23 ahead.

24 BY MR. SCHMIDT:

25 Q. May I go back to Page 6 of the opinion, please, just

1 the part that we were looking at? Do you see where there's
2 this reference to this September 11th, 2007 conference?

3 **A.** I do.

4 **Q.** Were you at that conference?

5 **A.** I was not.

6 **Q.** Okay. And you didn't hear what Michael Mapes had to
7 say at that conference?

8 **A.** I did not. I only saw the slides that were presented
9 at that conference.

10 **Q.** You didn't hear what Chris Zimmerman of ABDC had to say
11 at that conference?

12 **A.** I believe I was watching his testimony when he talked
13 about it.

14 **Q.** Okay. But you weren't at that conference?

15 MR. FARRELL: Objection, Your Honor.

16 THE WITNESS: Oh, I'm sorry. I --

17 THE COURT: Just a minute.

18 Mr. Farrell?

19 MR. FARRELL: Totem-pole hearsay, Your Honor.

20 MR. SCHMIDT: I'm not familiar with that concept.

21 MR. FARRELL: A Frank Cleckley term of multiple
22 layers of hearsay within hearsay. We now are referencing
23 what the people that are in this document are talking about
24 or said at another conference.

25 THE COURT: Well, this is cross examination and I

1 think this is a good faith reason to let him go ahead and
2 ask the questions, so I'll overrule that objection.

3 MR. SCHMIDT: Let me move on.

4 BY MR. SCHMIDT:

5 Q. And let's look at Page 9 of the opinion. And here,
6 there's a reference to your testimony in the third
7 paragraph.

8 Could we cull that third paragraph up?

9 Do you see where it says in this third paragraph, for
10 example, Agent Rafalski testified that after HD Smith filed
11 a Suspicious Order Report from March, 2006, he did nothing
12 to look into why the amount -- and then it continues -- was
13 identified as suspicious. Do you see that?

14 A. Yes.

15 Q. And, obviously, that's referencing your testimony in
16 this case?

17 A. That's correct.

18 Q. In response, George Euson testified that all HD Smith
19 did in terms of due diligence in 2006 and 2007 with respect
20 to suspicious orders was report them to DEA. Do you see
21 that?

22 A. That's correct.

23 Q. And then the Court found, of course, that is all the
24 regulation requires. Do you see that?

25 A. I don't see that the Court said that. My recollection

1 of this decision, it was a civil forfeiture case, Your
2 Honor, and what -- what was at issue here was whether there
3 was a willful blindness to the regulation or if the proof
4 was -- which later the Court ruled is that the distributor
5 had to have knowledge that there was criminal activity.

6 And going into the hearing, there was a ruling prior to
7 starting the case where Judge Lawson ruled that willful
8 blindness to the regulation would have been sufficient, but
9 seems there was -- it changed course at some point and the
10 actual ruling was whether or not the distributor had
11 knowledge of criminal activity.

12 **Q.** Sir, my question was simple. And why don't we
13 highlight it to make it easier. Do you see where it says
14 after Mr. Euson testified that all he did with suspicious
15 orders was report them? Do you see where it says, of
16 course, that is all the regulation requires? Do you see
17 that now that we've highlighted it?

18 **A.** That's the Court's opinion, yes, sir. I see what it
19 says there.

20 **Q.** I want to ask you a few other questions in this area
21 and then move on to another topic.

22 Can we go back to the demonstrative that you sponsored,
23 Mr. Rafalski, and specifically, to Slide 3 of that
24 demonstrative.

25 Here you list various guidance materials; is that

1 correct?

2 **A.** Yes.

3 **Q.** And here we see, as we were discussing earlier, the
4 Southwood decision of 2007. Do you see that?

5 **A.** Yes.

6 **Q.** And that was published in the Federal Register at that
7 time so people could see it, right?

8 **A.** Yes.

9 **Q.** We see some Rannazzisi letters, 2006 and 2007. Do you
10 see that?

11 **A.** I do.

12 **Q.** You're actually missing one in between, right?

13 **A.** Yes. It was a duplication of the first one.

14 **Q.** Okay. And then we see this Masters decision in 2017.
15 Do you see that?

16 **A.** Yes.

17 **Q.** And that's something you talked about in your report?

18 **A.** The Masters decision? Yes. Yes, sir.

19 **Q.** You cited it as a guidance material in this case,
20 right?

21 **A.** Yes, I did, Your Honor.

22 **Q.** And you actually worked on the case while you were at
23 DEA, right?

24 **A.** I did.

25 **Q.** And you specifically cite a D. C. Circuit opinion from

1 2017; is that right?

2 **A.** Yes, I do, Your Honor.

3 **Q.** All right. Let's cull that decision up. That's
4 DEF-WV-3532.

5 MR. SCHMIDT: And, again, Your Honor because it's
6 a court decision, we're not moving it into evidence. We're
7 asking the Court to take notice of it.

8 THE WITNESS: Thank you.

9 MR. SCHMIDT: Thank you.

10 And I will put it up on the screen absent objection.

11 BY MR. SCHMIDT:

12 **Q.** Do you see that this is a copy of the Masters decision
13 we were just looking at from the D. C. Circuit decided June,
14 2017?

15 **A.** Yes, I do, Your Honor.

16 **Q.** And I would like to show you just one portion of that
17 decision.

18 Could we go to Page 14, please? And if we could cull
19 out the paragraph in the bottom right corner.

20 And I want to look at the sentence that begins as noted
21 above. Do you see that sentence, Mr. Rafalski? As noted
22 above, the shipping requirement mandates that pharmaceutical
23 companies exercise due diligence before shipping any
24 suspicious order. Do you see that?

25 **A.** I do.

1 **Q.** And that's the do not ship requirement we've been
2 talking about, correct?

3 **A.** That's -- that's correct.

4 **Q.** Let's read the next sentence now. DEA first
5 articulated that requirement in Southwood, and Masters
6 claims that the administrator expanded on it here. Did I
7 read that correctly without the legal citation?

8 **A.** You did.

9 **Q.** And this opinion that you rely on, and cite in your
10 report, and actually worked on while at the DEA says DEA
11 first articulated that do not ship requirement in Southwood.
12 Remind us again when the Southwood decision was.

13 **A.** 2007.

14 **Q.** Thank you, sir. One more question on this topic. This
15 is in evidence for notice P-33. This is the first of the
16 two letters from Mr. Rannazzisi that you cited on your list
17 of guidance materials. You're familiar with this document,
18 sir?

19 **A.** I am, Your Honor.

20 **Q.** This is one of the two letters you cited as one of your
21 guidance materials?

22 **A.** It is.

23 **Q.** Dated September 27th, 2006?

24 **A.** Yes, it is, Your Honor.

25 **Q.** And it is from Joseph Rannazzisi, correct?

1 **A.** That's correct.

2 **Q.** So, this pre-dates that Southwood decision we just
3 talked about that the Masters decision says was the first
4 articulation of the do not ship requirement, correct?

5 **A.** I'd agree with that statement, Your Honor.

6 **Q.** All right. Let's look at this letter predating that
7 first articulation of the do not ship requirement. Would
8 you go with me to the second page, please? If we look at
9 the second paragraph, Mr. Rannazzisi writes, DEA recognizes
10 that the overwhelming majority of registered distributors
11 act lawfully and take appropriate measures to prevent
12 diversion. Did I read that correctly?

13 **A.** You read it correctly.

14 **Q.** Here's my question, sir. At this time, when Mr.
15 Rannazzisi said that the overwhelming majority of registered
16 distributors act lawfully and take appropriate measures to
17 prevent diversion from before this time period, before 2006,
18 is there any distributor you can point me to that blocked
19 every order it reported to the DEA?

20 **A.** I'm not aware of that, Your Honor.

21 **Q.** Switching gears. There's not a specific record
22 retention requirement under law for federal diligence files,
23 correct?

24 **A.** It doesn't -- in the Federal Register, it doesn't
25 specifically speak to due diligence files.

1 **Q.** It doesn't say how long they need to be maintained,
2 correct?

3 **A.** No. I believe that's one of the areas of the
4 maintenance of effective control is to prevent diversion to
5 keep those records to document your decisions and your
6 actions, but it doesn't specifically say that, Your Honor,
7 anywhere in the federal regulations.

8 **Q.** There are specific recordkeeping requirements for some
9 types of documents, right?

10 **A.** Yes, there are. They are a part of what's used to
11 control and to guide the -- keep the closed system intact,
12 required records.

13 **Q.** Just not for diligence files, correct?

14 **A.** There is not -- doesn't speak to due diligence files.

15 MR. SCHMIDT: Okay. Let's -- I have one more
16 small topic I can start. I'm not done. I've got more to
17 ask, but I can do one more small topic, Your Honor, or I can
18 --

19 THE COURT: We've got seven minutes before your
20 sand runs out of the glass here.

21 MR. SCHMIDT: I think I can get it done in the
22 seven minutes. If not, I'll pick up tomorrow.

23 Could we put back up the demonstrative? And could we
24 go to Page 7?

25 BY MR. SCHMIDT:

1 Q. This says number of transactions into Huntington and
2 Cabell County, West Virginia. Do you see that?

3 A. I do, Your Honor.

4 Q. Lists that number of transactions in the Huntington and
5 Cabell County for AmerisourceBergen, Cardinal Health,
6 McKesson, correct?

7 A. That's what it -- that's what it says, Your Honor.

8 Q. And it purports to do that for different periods of
9 time for each one of those, correct?

10 A. Yes. That was based on the transaction data that was
11 provided.

12 Q. Do you understand you're missing large numbers of
13 transactions into Huntington and Cabell on this slide?

14 A. Yes, I do, and the slide probably more accurately
15 should have said retail pharmacies.

16 Q. Okay. You're missing the VA, correct?

17 A. I am.

18 Q. You're missing other hospitals, correct?

19 A. Yes, hospitals. Only -- only data that's on display
20 for you, Your Honor, as retail pharmacies as customers.

21 Q. You're missing specialty pharmacies, like compounding
22 pharmacies?

23 A. Yes.

24 Q. Okay. And why did you limit this in this way? Why did
25 you exclude those categories when you wanted to talk about

1 number of transactions into Huntington and Cabell?

2 **A.** Well, the business activities for the hospitals and the
3 VA Hospital, I didn't find it to be applicable to the
4 diversion topic. The diversion is occurring at the retail
5 pharmacy level and to include a hospital wouldn't have been
6 a -- you know, a prudent way to look at the distribution.

7 **Q.** Is this the right set of data to be looking at, in your
8 view, retail pharmacy minus compound pharmacies minus
9 hospitals minus the VA?

10 **A.** I think, in looking at records, I've learned that some
11 compounders get involved with the dispensing of controlled
12 substances. So, in retrospect, I may want to have included
13 some compounders.

14 **Q.** So, this is incomplete?

15 **A.** Well --

16 **Q.** Let me try it this way. Is this complete in your view?

17 **A.** It's complete. I believe it's complete. It's retail
18 pharmacies. That's the target group for that data.

19 **Q.** Is it the right set of entities for you to include in
20 evaluating number of transactions in Huntington and Cabell
21 County?

22 **A.** That's what my report is based on and, yes, I believe
23 it is, Your Honor.

24 **Q.** And you limited it to hydrocodone and oxycodone. Are
25 those the two right prescription opioids to limit to in

1 evaluating transactions into Huntington and Cabell?

2 **A.** Yes, I believe they are.

3 **Q.** Let's go to Page 10, please. A few questions about
4 this. This slide is all dispensers, correct?

5 **A.** That's what that says.

6 **Q.** That includes the VA?

7 **A.** If it says all dispensers as the buyer, then it would.

8 **Q.** That includes hospitals?

9 **A.** If that's how it's labeled from Dr. McCann's
10 publication or his -- his production, then all buyers would
11 include that. I'm not -- I'm not positive that that's
12 exactly what that means. It may mean all buyers as retail
13 pharmacies, but --

14 **Q.** Okay.

15 **A.** So, I'm not sure, Your Honor.

16 **Q.** Okay. Do you know that the VA is over 75 percent of
17 McKesson's shipments to Huntington-Cabell, right?

18 **A.** I've heard that figure used. I don't know that for a
19 fact.

20 **Q.** Do you know how much lower those numbers would be if
21 you took out the VA?

22 **A.** I do not if, in fact, the VA is in there.

23 **Q.** You said that there was one policy change for McKesson
24 that occurred in 2008. Do you remember that?

25 **A.** Yes.

1 Q. I'll just put a mark here. What was the policy before
2 2008 called?

3 A. The DU45. They were publishing that on a monthly and a
4 daily basis.

5 Q. What was the name of the operating manual?

6 A. Section 55.

7 Q. What was it after 2008?

8 A. Actually, between 2007 and 2008, they had the Lifestyle
9 Drug Program.

10 Q. Okay. Where does that appear on this?

11 A. There should be a little gap between the -- the two --
12 it was a short period of time, 12 months or less. So,
13 there's a small gap there. Then after -- I guess maybe
14 closer to 2013, they started the new policy.

15 Q. Okay.

16 A. Or new procedure.

17 Q. So, there's actually a fourth policy now?

18 A. No.

19 Q. One, two, three, four?

20 A. No. There's only -- there's only one after 2008.

21 Q. Okay. Well, let me ask you about that. There was
22 Section 55, correct?

23 A. Yes.

24 Q. That's one. LDMP, that's two?

25 A. Yes.

1 Q. CSMP from 2008 to 2013, correct?

2 A. I believe a form of that runs -- runs all the way
3 through to 2018.

4 Q. Were there significant enhancements made to the CSMP in
5 2013?

6 A. Yes. The 2013 and also 2015, they incorporated a red
7 flag program and statistical/non-statistical data,
8 observable data. There were changes along the way.

9 Q. Tell me what those significant enhancements were in
10 that 2013-2014 window. One was red flags. What else?

11 A. The '15 was the -- was the -- the 2013, I don't think,
12 was the red flags. I believe they had a new investigative
13 policy put into place in regards to their SOMS. And then,
14 the 2015 would have been the red flags.

15 Q. Okay. What else was done in that 2013-2015 window that
16 we don't see reflected on this chart?

17 A. I believe there's some new changes to the reporting and
18 the recordkeeping, just from my recollection.

19 Q. You're aware that they began reporting more suspicious
20 orders, correct?

21 A. Yes.

22 Q. In fact, everywhere they blocked, correct?

23 A. Yes.

24 Q. You've not identified any orders they blocked following
25 this period, correct?

1 **A.** Yes, but there was no change to the threshold
2 calculation.

3 **Q.** Okay. You don't know that the way they calculated
4 thresholds changed?

5 **A.** It's my understanding they were doing the 12 months
6 trailing, picking the highest month, and then a ten-percent
7 buffer.

8 **Q.** You didn't know that they used new statistical tools
9 starting in 2014 and '15 to calculate thresholds and then
10 they brought in a company after that called AGI to calculate
11 thresholds?

12 **A.** Yes. I knew that they were starting to integrate the
13 AGI, but it wasn't clear to me whether or not they actually
14 were using AGI until later, in '17 and '18, and that's when
15 they rolled in the new program and were fully using the AGI
16 system.

17 **Q.** Do you know if they were conducting more diligence?

18 **A.** Through the AGI or --

19 **Q.** No. In this time period after 2013?

20 **A.** I believe there were more site visits and more
21 reporting. I don't -- I did not see an improvement in
22 reviews of threshold changes and due diligence of suspicious
23 orders, but I did see more compliance activity.

24 **Q.** And, in fact, there were more compliance -- more
25 employees specifically devoted to compliance, correct?

1 **A.** In looking -- in my reviews, I wouldn't have a way to
2 know that. I did hear some testimony where there was an
3 increase of hiring of employees.

4 **Q.** You didn't look at the manuals that actually lay out
5 how many new employees McKesson hired or the presentations
6 that talk about that?

7 **A.** If I did --

8 **Q.** Or the testimony?

9 COURT REPORTER: I'm sorry. I can only take one
10 at a time.

11 MR. SCHMIDT: My fault. I said or the testimony.

12 THE WITNESS: I remember -- I recall in the
13 testimony there was an increase hiring of more employees. I
14 don't recall the number.

15 BY MR. SCHMIDT:

16 **Q.** Okay. Last question. In terms of --

17 MR. SCHMIDT: And I can just end there, Your
18 Honor. We're over time. I'm sorry.

19 THE COURT: You can ask him the one more question,
20 Mr. Schmidt.

21 MR. SCHMIDT: My one question is always five, so
22 let me stop there. I know myself, Your Honor.

23 THE COURT: Well, I've found in my experience that
24 one more question from a lawyer never means one more.

25 MR. SCHMIDT: Yes. I have, too, Your Honor.

1 THE COURT: I can't think of a single time when it
2 is.

3 I'll see everybody at 9:00 in the morning.

4 MS. KEARSE: Your Honor, one thing. There's one
5 -- there's one demonstrative Mr. Schmidt showed that wasn't
6 -- was not marked, so I just want to -- I'll get with Mr.
7 Schmidt after, but I just want to make sure we get a copy.
8 It was the demonstrative for Method A. It wasn't marked,
9 but if we could get a copy of it. Thank you.

10 MR. SCHMIDT: Of course.

11 THE COURT: All right.

12 THE WITNESS: Thank you, Your Honor.

13 THE COURT: See you in the morning.

14 THE WITNESS: I will, I'll be here.

15 (Trial recessed at 5:02 p.m.)

16

17 CERTIFICATION:

18 I, Ayme A. Cochran, Official Court
19 Reporter, and I, Lisa A. Cook, Official Court Reporter,
20 certify that the foregoing is a correct transcript from
21 the record of proceedings in the matter of The City of
22 Huntington, et al., Plaintiffs vs. AmerisourceBergen
23 Drug Corporation, et al., Defendants, Civil Action No.
24 3:17-cv-01362 and Civil Action No. 3:17-cv-01665, as
25 reported on May 26, 2021.

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S\Ayme A. Cochran

Reporter

s\Lisa A. Cook

Reporter

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May 26, 2021

Date

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'			
'05 [1] - 253:2 '06 [2] - 41:12, 258:20 '07 [2] - 41:12, 258:20 '15 [2] - 275:11, 276:9 '16 [1] - 103:19 '17 [2] - 103:19, 276:14 '18 [2] - 103:19, 276:14 '6 [1] - 253:8 '84 [1] - 11:13 '86 [1] - 11:13 '87 [1] - 11:14 '95 [2] - 12:9, 45:3			
0			
0 [6] - 103:21, 104:19, 104:25, 105:6, 105:21, 228:24 00907 [2] - 2:5, 2:17			
1			
1 [17] - 36:8, 37:13, 41:2, 43:1, 92:6, 93:10, 103:14, 105:2, 180:2, 180:3, 186:19, 186:21, 192:14, 193:5, 216:20, 250:7, 250:20 1,000 [1] - 233:8 1,005,320 [1] - 100:13 1,056 [1] - 152:6 1,245,640 [1] - 100:15 10 [10] - 58:13, 58:14, 105:25, 155:10, 164:17, 164:19, 166:15, 166:22, 199:2, 273:3 10,000 [3] - 230:16, 231:6, 231:13 10,446,280 [1] - 100:23 10,477,680 [1] - 98:17 10-milligram [1] - 19:20 100 [6] - 71:14, 80:23, 157:19, 228:24, 233:7, 233:12 1001 [2] - 2:10, 4:6 1006 [2] - 7:16, 7:17			

188:22, 211:13, 211:16, 211:24, 212:17, 212:22, 212:24, 213:5, 221:6, 228:21, 229:13, 235:10, 261:17, 262:5 2021 [4] - 1:19, 7:4, 278:25, 279:6 21 [3] - 99:1, 176:6, 178:24 21,679,760 [1] - 100:24 219:10-13 [1] - 261:18 22 [1] - 99:2 22,582,020 [1] - 101:12 22.2 [1] - 219:16 2216 [1] - 3:7 225 [1] - 157:11 2254 [1] - 202:14 23 [3] - 176:18, 188:25 230 [2] - 164:16, 164:19 24 [1] - 176:22 24.8 [1] - 98:5 2402 [1] - 67:6 24th [1] - 8:16 25 [2] - 5:5, 183:2 25.2 [1] - 100:14 25301 [3] - 2:8, 3:13, 4:19 25322 [1] - 6:9 25338-3843 [1] - 5:15 25701 [1] - 3:10 26 [4] - 1:19, 7:4, 278:25, 279:6 2628 [2] - 124:23, 126:20 27th [1] - 268:23 28 [3] - 3:15, 4:3, 4:9 29 [1] - 105:24 29.4 [1] - 98:4 290 [1] - 67:5 29464 [3] - 3:15, 4:4, 4:9 29th [2] - 212:17, 212:23 2nd [1] - 213:5	3,763,580 [1] - 98:4 3,983,350 [1] - 49:24 30 [2] - 23:6, 24:20 30-day [1] - 239:16 30-milligram [1] - 20:10 3076 [2] - 118:14, 119:11 30th [1] - 22:19 3100 [2] - 6:5, 6:12 316 [1] - 2:13 32 [1] - 105:12 325 [1] - 71:5 32502 [1] - 2:14 33.4 [1] - 100:15 34 [1] - 105:12 34,482 [1] - 181:19 35 [2] - 163:17, 258:13 36 [5] - 150:18, 163:6, 163:15, 163:21, 166:11 360 [5] - 124:3, 124:7, 124:12, 124:23, 126:12 3843 [1] - 5:14 3:12 [1] - 199:4 3:17-cv-01362 [2] - 1:5, 278:24 3:17-cv-01665 [2] - 1:11, 278:24 3rd [2] - 211:13, 211:16	5,616,380 [1] - 98:5 50 [4] - 18:6, 152:23, 153:8, 153:9 500 [3] - 95:3, 95:7, 233:7 52.7 [1] - 101:4 55 [2] - 274:6, 274:22 55.7 [1] - 100:6 553 [1] - 6:8 56 [1] - 3:4 56th [1] - 3:5 5:02 [1] - 278:15 5:15 [1] - 8:8	8 8 [5] - 34:10, 36:8, 43:2, 50:22, 140:6 8,000 [8] - 93:22, 94:1, 94:7, 94:8, 94:13, 100:19, 230:16, 231:6 8,360,740 [1] - 100:3 80 [5] - 18:25, 71:9, 71:17, 248:12, 248:16 80-90 [1] - 208:17 80-milligram [1] - 19:19 801 [1] - 3:10 801(d)(2)(D) [1] - 9:7 805,300 [1] - 98:10 80s [1] - 71:14 81.5 [2] - 98:20, 100:23 81.8 [1] - 98:17 81:23 [1] - 188:23 82.5 [1] - 97:3 82:1 [1] - 188:23 83.4 [1] - 98:19 83.5 [1] - 100:12 850 [1] - 5:12 86 [2] - 105:9, 105:12 87 [1] - 226:20 87.4 [1] - 97:6 87.9 [3] - 97:5, 219:13, 219:20	97.9 [1] - 101:20 98 [1] - 101:16 99 [6] - 121:14, 152:24, 153:5, 216:19, 228:22 99.8 [1] - 101:13 99.99 [3] - 121:22, 122:2, 122:6 9:00 [2] - 7:4, 278:3 9:49 [1] - 43:11 9th [1] - 2:10
3 3 [6] - 34:19, 43:1, 152:15, 164:17, 164:19, 265:23 3,261,250 [1] - 97:6 3,501,970 [1] - 97:4 3,648,650 [1] - 101:20 3,713,000 [1] - 101:18 3,732,930 [1] - 49:23	4 4 [5] - 43:1, 103:12, 103:15, 125:25, 148:3 40 [1] - 18:5 40,000 [2] - 80:21, 80:23 40.5 [1] - 98:9 400 [4] - 71:16, 181:19, 219:20, 220:8 401 [2] - 2:10, 4:6 405 [1] - 2:7 416 [1] - 206:4 42432 [1] - 7:17 45 [2] - 103:9, 103:24 48 [1] - 12:24	6 6 [10] - 34:10, 43:1, 44:24, 92:12, 103:18, 137:7, 256:25, 259:25, 260:1, 262:25 60.4 [1] - 98:23 600 [1] - 2:13 63.3 [1] - 98:24 64 [1] - 98:11 642 [1] - 173:17 65.3 [1] - 100:3 65.9 [1] - 98:8 66.6 [1] - 101:5 69.4 [1] - 100:4 6th [3] - 3:5, 67:11, 118:15	9 9 [5] - 34:11, 56:17, 125:10, 125:25, 264:5 9,000 [2] - 230:16, 231:6 9,500 [2] - 230:16, 231:6 9,567,580 [1] - 100:6 9-17 [1] - 228:22 90 [3] - 152:23, 217:3, 217:15 90.2 [1] - 101:2 90.6 [1] - 96:22 901 [1] - 4:18 91.1 [1] - 96:25 91436 [1] - 3:18 92,915 [2] - 49:8, 104:15 92.6 [1] - 98:21 93.1 [1] - 97:2 93.2 [1] - 101:19 95.8 [1] - 100:24 96.2 [1] - 101:15 97.3 [1] - 101:11	A A-Plus [7] - 151:17, 151:23, 152:13, 152:15, 152:17, 152:20, 153:3 a.m [2] - 7:4, 43:11 abandon [1] - 87:7 ABDC [16] - 51:23, 73:21, 85:15, 129:9, 130:9, 131:7, 131:21, 150:24, 151:22, 206:13, 207:2, 227:14, 227:22, 250:25, 251:14, 263:10 ability [12] - 12:1, 16:15, 20:18, 84:4, 84:5, 86:17, 148:15, 175:15, 175:23, 176:6, 176:19, 178:25 able [36] - 21:13, 29:4, 44:15, 46:19, 46:23, 47:3, 49:25, 50:6, 50:10, 52:11, 54:25, 67:21, 77:10, 79:15, 83:12, 83:19, 95:22, 96:1, 104:17, 123:11, 126:9, 156:3, 156:11, 156:19, 160:10, 162:16, 167:21, 174:4, 180:23, 184:17, 185:20, 186:2, 213:21, 213:23, 238:5, 239:11 absent [2] - 256:15, 267:10 absolutely [2] - 109:21, 165:10 abstract [2] - 77:16, 88:12 abuse [10] - 139:19, 139:24, 141:8, 143:10, 143:14, 143:19, 184:25,

<p>193:6, 193:10, 193:11</p> <p>Abuse [2] - 126:14, 138:14</p> <p>academic [1] - 15:15</p> <p>academics [1] - 236:14</p> <p>academy [3] - 15:12, 15:13, 158:23</p> <p>accept [1] - 33:3</p> <p>acceptance [1] - 236:12</p> <p>accepted [2] - 15:11, 242:1</p> <p>accepting [1] - 243:5</p> <p>access [17] - 28:5, 149:3, 166:15, 166:22, 167:12, 167:15, 167:16, 167:17, 177:4, 177:7, 177:13, 177:15, 177:19, 178:14, 191:14, 200:2, 201:1</p> <p>accomplish [1] - 29:4</p> <p>accordance [2] - 200:6, 201:7</p> <p>According [2] - 168:6, 196:2</p> <p>according [1] - 253:4</p> <p>account [5] - 46:9, 106:25, 241:17, 241:20, 241:23</p> <p>accountability [1] - 191:23</p> <p>accounted [1] - 153:19</p> <p>Accounting [1] - 138:13</p> <p>accuracy [4] - 52:15, 144:18, 154:23, 183:8</p> <p>accurate [15] - 63:3, 132:20, 141:12, 144:3, 150:18, 150:19, 156:18, 162:18, 178:22, 201:9, 209:2, 210:19, 243:12, 245:16, 256:23</p> <p>accurately [4] - 63:8, 158:20, 202:2, 271:14</p> <p>acetaminophen [1] - 71:6</p> <p>ACKERMAN [7] - 2:9, 8:4, 8:14, 8:21, 9:22, 9:24, 53:10</p> <p>Ackerman [1] - 53:9</p> <p>acknowledge [3] -</p>	<p>137:5, 221:16, 225:25</p> <p>acknowledged [1] - 252:14</p> <p>act [8] - 135:15, 162:16, 178:17, 178:20, 178:22, 184:6, 269:11, 269:16</p> <p>Act [4] - 38:9, 248:23, 249:1, 249:13</p> <p>acting [3] - 129:15, 182:25, 246:4</p> <p>Action [6] - 1:4, 1:10, 118:25, 119:3, 278:23, 278:24</p> <p>action [13] - 25:9, 29:7, 37:4, 39:9, 40:20, 76:12, 206:12, 233:9, 246:7, 252:1, 252:9, 252:10, 261:12</p> <p>Actions [1] - 192:10</p> <p>actions [4] - 19:4, 40:25, 41:14, 270:6</p> <p>active [5] - 69:25, 71:9, 71:20, 261:9, 261:11</p> <p>activities [2] - 195:20, 272:2</p> <p>activity [6] - 22:25, 23:19, 36:25, 265:5, 265:11, 276:23</p> <p>actual [14] - 15:25, 48:1, 52:18, 68:1, 69:25, 77:11, 83:6, 102:18, 153:13, 250:10, 250:19, 255:8, 265:10</p> <p>Adams [1] - 67:6</p> <p>add [4] - 51:19, 78:22, 227:2, 246:17</p> <p>Adderall [1] - 84:8</p> <p>addition [2] - 31:20, 119:17</p> <p>address [3] - 52:16, 67:6, 151:3</p> <p>Address [1] - 138:14</p> <p>addressed [2] - 39:23, 153:24</p> <p>adequate [1] - 148:18</p> <p>adequately [2] - 142:13, 168:2</p> <p>adjust [4] - 242:22, 245:19, 247:15, 247:22</p> <p>adjusted [1] - 247:10</p> <p>adjusting [1] - 243:11</p> <p>Administration [4] - 13:1, 45:17, 118:18,</p>	<p>118:21</p> <p>Administration's [1] - 163:11</p> <p>administrative [12] - 15:21, 17:18, 18:10, 20:14, 20:15, 20:20, 23:16, 25:9, 28:11, 37:4, 39:9, 41:14</p> <p>administrator [3] - 180:11, 182:25, 268:6</p> <p>admissibility [3] - 9:20, 31:22, 63:11</p> <p>admissible [5] - 43:25, 51:11, 52:20, 53:12, 127:3</p> <p>admit [6] - 9:19, 9:21, 43:15, 43:22, 99:10, 120:2</p> <p>admitted [17] - 8:2, 8:12, 8:20, 8:22, 9:25, 34:8, 34:9, 34:11, 44:1, 52:18, 53:11, 63:24, 138:22, 162:19, 174:21, 192:7, 198:2</p> <p>admittedly [1] - 104:15</p> <p>adopted [3] - 215:2, 224:11, 226:8</p> <p>advance [2] - 20:9, 32:6</p> <p>advise [1] - 42:7</p> <p>advised [1] - 246:2</p> <p>advocate [1] - 188:4</p> <p>affirmatively [1] - 117:19</p> <p>after-the-fact [2] - 65:8, 66:7</p> <p>agency [1] - 245:22</p> <p>Agency [1] - 118:25</p> <p>agent [3] - 16:4, 16:5, 252:15</p> <p>Agent [2] - 259:14, 264:10</p> <p>agents [3] - 114:25, 166:23, 260:10</p> <p>aggregate [2] - 180:4, 181:18</p> <p>aggressive [1] - 142:10</p> <p>AGI [5] - 276:10, 276:13, 276:14, 276:15, 276:18</p> <p>ago [6] - 162:3, 167:21, 184:23, 190:25, 192:1</p> <p>agree [63] - 32:19, 33:12, 39:20, 117:10, 117:22,</p>	<p>117:24, 118:5, 119:8, 121:2, 121:3, 121:8, 121:9, 121:18, 122:3, 122:4, 122:7, 122:23, 123:18, 125:15, 125:16, 140:2, 140:3, 147:14, 150:10, 150:13, 154:18, 156:2, 156:20, 157:3, 157:4, 157:17, 157:19, 157:20, 171:4, 171:6, 177:18, 186:13, 186:23, 188:3, 188:8, 188:11, 196:7, 198:19, 198:22, 200:2, 200:5, 204:2, 204:15, 207:24, 208:5, 208:10, 208:12, 209:24, 221:20, 222:1, 222:4, 229:23, 235:8, 237:5, 249:12, 250:9, 260:24, 269:5</p> <p>agreed [4] - 8:7, 52:25, 87:3, 220:25</p> <p>agreement [1] - 21:25</p> <p>Agreement [3] - 22:2, 22:23, 23:3</p> <p>ahead [34] - 14:14, 32:22, 33:11, 35:14, 40:13, 40:16, 46:1, 53:21, 63:13, 69:19, 74:5, 77:9, 79:6, 79:7, 80:10, 81:14, 86:12, 86:22, 90:12, 91:11, 91:25, 100:9, 106:20, 107:19, 110:22, 166:6, 176:18, 197:18, 198:3, 221:24, 240:20, 254:11, 262:23, 264:1</p> <p>Aid [5] - 106:2, 106:3, 106:4, 106:9, 136:4</p> <p>Aid's [1] - 106:13</p> <p>Aids [1] - 215:19</p> <p>Airport [1] - 11:10</p> <p>al [4] - 1:7, 1:13, 278:22, 278:23</p> <p>alarm [6] - 89:4, 89:5, 89:8, 97:14, 102:2</p> <p>algorithm [4] - 77:18, 83:7, 84:14, 213:13</p> <p>algorithms [3] - 87:1, 211:2, 212:25</p>	<p>allegations [1] - 171:23</p> <p>allege [2] - 145:20, 153:2</p> <p>alleged [3] - 146:3, 146:4, 146:12</p> <p>Allison [1] - 7:25</p> <p>allow [9] - 43:19, 43:21, 60:20, 63:13, 79:5, 111:14, 177:4, 177:6, 243:10</p> <p>allowed [3] - 24:19, 144:9, 243:4</p> <p>allowing [2] - 220:4, 220:7</p> <p>allows [1] - 84:9</p> <p>almost [1] - 243:25</p> <p>alone [2] - 21:8, 232:21</p> <p>amending [1] - 203:14</p> <p>amendment [2] - 203:17, 203:21</p> <p>America [7] - 11:20, 16:12, 18:18, 38:22, 123:12, 183:18, 244:12</p> <p>American [1] - 120:23</p> <p>AMERISOURCEBER GEN [2] - 1:7, 1:13</p> <p>AmerisourceBergen [38] - 6:2, 29:24, 45:10, 47:21, 47:24, 49:3, 49:6, 49:16, 50:22, 54:15, 54:24, 55:6, 55:13, 55:16, 56:7, 56:13, 58:7, 59:24, 96:18, 96:20, 98:2, 98:3, 98:16, 100:2, 100:22, 101:10, 102:11, 103:1, 103:4, 103:7, 107:4, 107:21, 108:25, 110:3, 110:7, 111:12, 271:5, 278:22</p> <p>amount [29] - 20:10, 23:5, 55:19, 57:12, 69:25, 80:18, 83:4, 84:6, 88:7, 88:17, 89:2, 91:15, 93:25, 95:1, 95:13, 95:16, 95:17, 96:22, 152:19, 182:3, 186:17, 191:11, 233:4, 233:7, 247:14, 248:18, 248:19, 264:12</p> <p>amounts [8] - 39:8, 75:15, 95:18, 95:21, 151:6, 180:9,</p>
--	---	--	---	---

181:16, 215:17 ample [1] - 63:12 analyses [4] - 201:15, 209:20, 210:8, 210:16 analysis [11] - 43:18, 79:10, 92:25, 127:23, 128:25, 129:4, 150:22, 151:14, 152:19, 216:6, 247:13 Analysis [1] - 175:5 analyze [3] - 26:19, 175:16, 175:20 analyzed [2] - 140:11, 179:10 analyzing [2] - 114:20, 200:11 ANDREW [1] - 5:10 ANNE [1] - 4:2 ANNIE [1] - 3:14 annual [1] - 144:9 anomalies [1] - 132:12 Answer [1] - 187:5 answer [41] - 32:13, 33:8, 33:9, 36:20, 36:22, 66:1, 128:4, 128:6, 128:7, 140:5, 145:10, 157:23, 160:3, 160:22, 160:25, 162:7, 164:21, 165:24, 166:3, 166:5, 169:2, 171:16, 171:20, 172:20, 183:11, 189:5, 202:1, 212:25, 217:22, 221:14, 228:25, 229:1, 229:2, 229:19, 229:21, 233:22, 235:19, 235:24, 236:3, 261:21, 262:16 answered [3] - 59:15, 171:1, 172:10 answering [3] - 115:19, 115:20, 160:17 answers [3] - 39:21, 93:4, 172:1 ANTHONY [1] - 2:6 anthony [1] - 262:21 anytime [4] - 227:10, 231:9, 245:17, 247:3 apart [1] - 48:9 apologize [3] - 91:3, 216:13, 242:21 apparent [1] - 55:2 appear [5] - 146:15, 239:2, 246:18, 255:8, 274:10 APPEARANCES [6] - 2:1, 3:1, 5:1, 5:6, 6:1, 6:10 appellate [2] - 85:6, 236:24 Appendix [1] - 152:6 applicable [2] - 50:7, 272:3 applicant [5] - 171:19, 171:22, 171:25, 172:10, 172:12 applicant's [1] - 171:20 applicants [2] - 168:3, 168:13 application [3] - 171:23, 172:1, 235:5 applications [2] - 12:25, 170:20 applied [10] - 9:4, 84:21, 88:25, 89:20, 92:23, 92:24, 173:4, 235:8, 245:1 applies [2] - 194:24, 243:2 apply [3] - 114:10, 114:13, 236:22 applying [3] - 100:20, 171:1, 236:16 appreciate [1] - 99:18 approach [11] - 8:1, 53:23, 64:1, 118:10, 124:20, 152:8, 190:17, 193:1, 197:8, 214:1, 214:2 approached [2] - 11:15, 224:9 approaches [1] - 141:24 appropriate [10] - 30:22, 43:7, 74:11, 77:5, 106:23, 162:17, 221:1, 256:13, 269:11, 269:16 appropriately [2] - 156:16, 180:24 approval [3] - 138:3, 138:5, 141:3 approved [1] - 259:17 approves [1] - 171:23 approving [1] - 9:1 approximation [1] - 205:17 APQ [3] - 180:3, 181:18, 183:1 April [6] - 8:16, 67:14, 68:2, 69:4, 71:24, 148:1 arbitrarily [2] - 184:13, 239:17 arbitrary [2] - 95:3, 183:21 Arch [2] - 6:6, 6:13 ARCOS [39] - 45:15, 61:4, 61:10, 61:11, 61:15, 61:16, 61:18, 65:7, 73:6, 75:19, 76:16, 93:2, 114:6, 114:11, 114:21, 115:2, 173:7, 173:11, 173:25, 174:23, 174:25, 175:8, 175:16, 175:19, 176:2, 176:7, 176:19, 177:4, 177:13, 177:19, 191:2, 199:25, 200:1, 200:2, 200:6, 201:1, 201:19, 202:4 area [14] - 11:21, 15:21, 17:20, 19:3, 20:7, 42:12, 56:3, 59:8, 94:25, 117:25, 130:2, 161:1, 194:10, 265:20 areas [4] - 15:21, 64:23, 160:4, 270:3 argue [1] - 252:13 argument [2] - 30:21, 86:14 argumentative [4] - 145:5, 145:7, 147:8, 239:7 arguments [1] - 30:19 arising [1] - 109:3 arrest [1] - 16:6 arrived [1] - 18:15 arriving [1] - 28:12 articulated [6] - 31:10, 32:1, 74:7, 162:3, 268:5, 268:11 articulation [2] - 269:4, 269:7 ASHLEY [1] - 5:3 Ashworth [1] - 8:7 Aside [1] - 22:3 assembled [1] - 26:6 assertions [1] - 73:20 assessment [3] - 96:17, 218:16, 218:18 assigned [3] - 17:20, 18:16, 22:5 assignment [4] - 15:18, 18:10, 160:2, 160:3 assignments [1] - 15:22 assist [8] - 18:16, 27:4, 34:1, 36:2, 44:21, 47:10, 50:18, 82:5 associate [1] - 168:6 association [1] - 37:16 assume [2] - 73:21, 89:3 assuming [2] - 97:8, 102:3 assumption [18] - 101:25, 217:5, 225:24, 226:17, 226:22, 227:4, 227:6, 235:1, 236:8, 236:13, 236:22, 237:22, 238:1, 238:3, 241:11, 243:2, 243:3, 245:3 assumptions [5] - 212:7, 212:13, 212:16, 213:22, 245:1 AT [1] - 1:2 attempt [5] - 54:14, 54:19, 87:6, 221:9, 236:20 attempted [4] - 13:4, 52:12, 52:17, 223:18 attempting [3] - 87:2, 88:3, 88:4 attempts [1] - 86:9 attorney [1] - 39:1 Attorney [1] - 38:8 Attorney's [1] - 21:24 attorneys [4] - 26:10, 26:11, 174:1, 254:19 attributable [1] - 153:3 audits [2] - 200:13, 200:14 August [10] - 157:6, 157:11, 211:13, 211:16, 212:17, 212:23, 213:5, 231:22, 231:25, 232:19 author [2] - 197:22, 197:23 authorities [1] - 185:1 authority [1] - 143:2 authorized [1] - 181:15 automatically [1] - 251:1 Automation [1] - 174:24 available [13] - 34:24, 46:21, 47:1, 47:6, 47:22, 50:3, 50:8, 50:13, 59:5, 82:19, 102:5, 173:24, 223:15 average [43] - 62:3, 62:4, 62:6, 68:4, 68:6, 68:9, 68:12, 69:5, 69:9, 70:1, 70:2, 70:12, 73:10, 85:12, 85:15, 86:8, 92:9, 92:10, 92:14, 92:18, 92:19, 92:20, 93:1, 93:3, 93:11, 93:13, 93:17, 98:13, 98:14, 99:22, 99:23, 129:6, 176:14, 176:25, 177:1, 179:1, 179:2 Avin [1] - 3:7 avoid [1] - 112:10 avoiding [1] - 24:18 aware [70] - 39:13, 53:16, 53:17, 114:16, 121:13, 121:20, 124:3, 129:17, 131:6, 131:21, 132:24, 138:8, 138:10, 147:3, 149:14, 149:17, 149:19, 149:24, 151:5, 158:4, 158:7, 162:12, 162:15, 165:20, 177:6, 179:4, 179:7, 179:14, 179:17, 181:3, 181:6, 181:23, 194:20, 194:22, 201:17, 203:10, 203:13, 203:16, 203:20, 203:23, 204:12, 206:16, 206:20, 207:2, 207:5, 213:8, 213:12, 213:20, 222:8, 224:19, 236:7, 236:10, 242:6, 248:17, 248:21, 249:12, 250:18, 250:25, 251:7, 251:24, 255:12, 259:10, 259:14, 259:16, 259:18, 259:19, 269:20, 275:19 awry [1] - 72:9 axis [7] - 55:21, 55:22, 55:24, 57:4, 57:5				
--	--	--	--	--

Ayme [2] - 6:17, 278:18	bears [3] - 122:23, 122:25, 182:8	219:19	box [7] - 48:17, 55:9, 75:13, 194:13, 195:2, 195:6, 195:9	53:25, 59:23, 62:18, 63:17, 64:9, 66:5, 66:22, 69:2, 70:10, 72:17, 72:21, 74:15, 75:24, 77:7, 78:8, 79:9, 80:11, 81:19, 82:14, 86:24, 87:10, 91:4, 92:2, 94:4, 96:9, 99:16, 99:21, 100:17, 103:2, 106:22, 107:14, 107:20, 108:10, 108:22, 110:4, 110:23, 111:16, 112:21, 114:1, 115:13, 118:12, 120:4, 124:21, 126:3, 127:7, 127:15, 128:10, 138:23, 139:10, 145:14, 147:21, 152:10, 155:4, 161:3, 165:3, 165:15, 166:7, 172:21, 174:12, 174:22, 178:12, 188:1, 190:12, 190:24, 192:8, 193:4, 197:10, 198:6, 199:7, 200:24, 203:3, 207:15, 207:21, 209:7, 211:25, 214:5, 216:2, 217:25, 219:4, 221:19, 221:25, 231:2, 232:4, 234:19, 235:13, 238:12, 243:17, 246:15, 262:24, 264:4, 267:11, 270:25, 277:15
B	became [2] - 11:13, 11:14	bigger [1] - 81:9	boxes [3] - 193:24, 194:1, 194:5	by-product [1] - 184:5
background [7] - 10:22, 20:13, 22:22, 25:14, 120:6, 123:23, 170:23	becomes [1] - 57:1	bit [13] - 8:5, 10:21, 22:20, 48:10, 59:20, 61:13, 62:24, 65:3, 67:3, 88:13, 93:20, 122:19, 158:11	break [8] - 43:5, 43:9, 81:10, 81:11, 158:11, 173:22, 198:24, 209:6	
backing [1] - 92:14	BEFORE [1] - 1:17	black [2] - 34:7, 58:23	Bridgeside [3] - 3:15, 4:3, 4:9	
backside [1] - 55:10	began [8] - 11:20, 15:6, 21:20, 22:14, 250:25, 254:12, 258:15, 275:19	blame [1] - 154:15	Brief [1] - 141:19	
backwards [1] - 88:4	begin [2] - 22:6, 45:9	blank [1] - 130:23	briefing [3] - 254:25, 255:5, 259:3	
bar [12] - 45:7, 45:8, 45:11, 45:13, 45:15, 58:3, 58:4, 58:5, 58:17, 58:22, 87:22, 94:7	beginning [4] - 55:12, 105:7, 105:22, 154:11	blindness [2] - 265:3, 265:8	briefings [9] - 252:23, 253:2, 253:5, 254:12, 254:15, 255:11, 258:16, 258:19, 258:23	
Barber [2] - 38:24, 38:25	begins [2] - 163:24, 267:20	block [13] - 30:6, 59:20, 79:11, 79:16, 79:21, 81:9, 97:10, 97:20, 109:2, 207:24, 208:3, 251:3, 252:2	briefly [6] - 16:18, 25:7, 35:22, 37:12, 70:25, 104:1	
Barber's [1] - 39:4	behalf [6] - 41:18, 62:24, 95:15, 111:11, 112:18, 223:23	blocked [10] - 42:23, 76:19, 96:3, 97:8, 207:3, 207:7, 251:5, 269:18, 275:22, 275:24	bring [7] - 16:22, 44:7, 64:4, 96:8, 102:25, 122:14, 148:25	
Baron [1] - 3:17	belaboring [3] - 34:14, 42:1, 113:11	blocking [5] - 29:5, 89:21, 208:7, 251:1, 258:7	bringing [1] - 7:25	
bars [5] - 56:18, 58:16, 58:22, 58:23, 92:15	belief [3] - 84:8, 104:13, 204:1	blocks [8] - 54:3, 54:6, 54:7, 54:10, 54:19, 89:22, 96:14, 97:21	broad [3] - 187:1, 187:7, 187:8	
base [3] - 53:15, 94:14, 247:9	beliefs [1] - 118:1	blow [1] - 192:16	broadly [1] - 13:18	
based [41] - 51:7, 51:9, 61:11, 62:15, 65:8, 70:21, 80:15, 80:25, 83:11, 85:13, 87:15, 88:20, 103:5, 106:16, 130:5, 180:20, 180:24, 185:19, 188:6, 215:17, 216:23, 217:5, 217:18, 218:17, 218:21, 220:9, 220:10, 224:14, 228:15, 228:17, 238:15, 241:9, 241:13, 242:23, 247:15, 250:3, 250:13, 253:15, 255:13, 271:10, 272:22	belong [1] - 37:17	blue [4] - 45:11, 56:8, 56:10, 194:5	brought [2] - 148:22, 276:10	
basic [2] - 22:8, 180:9	below [13] - 54:3, 68:2, 71:7, 75:17, 95:16, 118:25, 119:1, 141:18, 176:14, 179:2, 195:9, 205:23, 233:4	Blvd [3] - 3:15, 4:3, 4:9	Budd [1] - 3:17	
basing [1] - 247:8	bench [1] - 43:16	board [8] - 171:24, 171:25, 174:23, 193:1, 214:1, 222:5, 222:14, 241:5	buffer [1] - 276:7	
basis [25] - 51:14, 53:2, 53:19, 61:9, 63:9, 69:3, 70:5, 73:5, 94:1, 109:21, 145:6, 172:16, 175:24, 176:3, 176:9, 176:13, 179:1, 207:18, 216:25, 225:11, 245:24, 246:8, 274:4	BENCH [1] - 1:16	Board [1] - 131:15	built [2] - 75:14, 80:3	
Bates [1] - 66:15	benchmark [1] - 70:15	body [1] - 205:18	bullets [1] - 194:13	
Baylen [1] - 2:13	berth [1] - 30:20	bollixed [1] - 110:17	bump [1] - 93:20	
bear [1] - 123:18	beside [1] - 154:19	Bonasso [1] - 5:14	Burling [1] - 5:11	
	best [3] - 115:22, 223:10, 249:18	bottle [2] - 48:16, 48:19	business [5] - 23:9, 62:4, 84:11, 150:2, 272:2	
	better [4] - 37:10, 40:5, 89:4, 160:11	bottles [2] - 48:7, 48:19	businesses [1] - 17:19	
	between [28] - 9:12, 36:18, 41:4, 49:21, 52:13, 58:6, 58:8, 65:4, 80:5, 89:11, 104:18, 104:23, 105:14, 149:19, 161:1, 186:22, 189:17, 201:20, 215:20, 216:10, 219:25, 226:19, 228:24, 230:5, 238:19, 266:12, 274:8, 274:11	bottom [24] - 54:2, 56:18, 56:19, 56:23, 58:15, 58:21, 66:16, 67:16, 68:8, 87:20, 97:4, 98:22, 101:3, 139:14, 139:17, 140:9, 140:23, 142:22, 179:24, 188:24, 193:24, 197:12, 260:2, 267:19	buy [8] - 12:18, 12:19, 48:12, 48:16, 48:18, 48:19	C
	Between [1] - 186:21	bought [1] - 80:23	buy-out [2] - 12:18, 12:19	CA [1] - 3:18
	beyond [1] - 233:19	Boulevard [1] - 3:18	buyer [1] - 273:7	Cabell [78] - 3:2, 9:13, 42:11, 44:12, 46:20, 46:25, 47:5, 50:2, 54:25, 56:4, 57:18, 59:4, 59:8, 97:17, 103:5, 106:5, 106:10, 106:14, 106:25, 107:6, 107:24, 108:6, 108:17, 109:3, 110:9, 111:1, 111:21, 112:6, 112:25, 124:8, 124:12, 125:3,
	bifurcate [1] - 52:12	Box [2] - 5:14, 6:8	buyers [2] - 273:10, 273:12	
	bifurcation [1] - 52:25		Buzzeeo [1] - 261:6	
	big [5] - 19:3, 208:14, 208:16, 219:18,		BY [112] - 10:16, 14:23, 21:19, 25:6, 26:4, 27:9, 32:25, 33:18, 34:13, 35:15, 36:7, 37:9, 40:17, 42:6, 44:5, 45:2, 46:2, 46:18, 47:16,	

<p>125:8, 127:16, 127:17, 128:12, 128:23, 129:5, 129:10, 134:13, 134:21, 135:9, 135:23, 136:1, 144:16, 149:16, 150:15, 150:23, 151:19, 152:20, 153:2, 154:5, 171:16, 172:23, 179:5, 179:12, 185:16, 186:3, 186:15, 194:23, 206:14, 206:17, 206:22, 207:22, 208:21, 211:4, 241:24, 242:7, 244:1, 244:4, 244:8, 271:2, 271:5, 271:13, 272:1, 272:20, 273:1, 273:17</p> <p>CABELL [1] - 1:10 cabell [1] - 2:2 Cabell/Huntington [1] - 127:17 cabinet [2] - 195:14, 196:6 cake [1] - 94:24 calculate [8] - 62:3, 62:6, 75:15, 238:20, 250:5, 276:9, 276:10 calculated [3] - 68:2, 83:17, 276:3 calculating [1] - 122:10 calculation [2] - 250:10, 276:2 calculations [3] - 115:5, 250:7, 250:19 calendar [2] - 180:11, 238:20 CALLAS [1] - 6:7 camera [1] - 66:20 Cameron [1] - 58:4 campaign [2] - 141:21, 141:22 CAMPBELL [1] - 6:14 cancelled [1] - 76:19 Cancer [1] - 204:17 cancer [2] - 142:1, 217:6 cannot [3] - 52:2, 144:20, 206:15 cap [8] - 72:4, 88:10, 89:18, 93:23, 95:11, 97:21, 97:22, 99:24 capabilities [1] - 96:5 capita [1] - 176:3</p>	<p>Capitol [1] - 2:7 capture [2] - 26:20, 55:9 Cardinal [70] - 4:11, 5:2, 7:21, 29:24, 38:3, 40:23, 45:13, 45:22, 46:5, 46:6, 47:21, 49:6, 49:11, 55:7, 55:8, 55:17, 57:1, 57:10, 57:15, 57:21, 57:24, 58:7, 59:24, 62:24, 64:17, 66:7, 66:11, 67:8, 67:22, 68:3, 68:11, 69:3, 70:15, 70:23, 71:19, 71:24, 72:25, 73:19, 85:16, 85:21, 85:25, 86:4, 86:6, 96:19, 97:1, 98:2, 98:7, 98:20, 100:6, 100:25, 101:14, 102:12, 104:14, 105:15, 108:3, 109:1, 129:9, 130:10, 131:7, 131:21, 150:24, 151:22, 201:22, 206:13, 207:2, 227:14, 227:22, 250:25, 251:14, 271:5 Cardinal's [2] - 63:2, 233:23 care [3] - 141:25, 216:8, 218:8 career [2] - 12:14, 160:15 careful [1] - 78:9 carefully [1] - 187:22 Carey [1] - 4:17 Carolina [1] - 176:9 carry [5] - 16:6, 156:3, 167:22, 168:18, 189:1 carve [1] - 144:19 case [102] - 13:24, 19:5, 19:8, 19:9, 19:19, 20:2, 20:3, 21:5, 22:1, 22:11, 22:16, 22:18, 23:1, 23:5, 24:15, 25:5, 25:16, 26:13, 28:6, 28:10, 29:10, 31:13, 33:20, 39:6, 39:18, 40:19, 41:19, 41:23, 48:13, 53:15, 59:14, 61:20, 62:5, 81:4, 93:24, 95:19, 115:25, 116:1, 116:2, 116:5, 124:9,</p>	<p>127:20, 128:24, 130:12, 132:24, 136:11, 136:20, 137:14, 147:2, 147:4, 149:15, 154:17, 179:16, 182:6, 186:10, 188:13, 188:16, 189:4, 200:19, 201:18, 202:5, 210:3, 211:12, 211:15, 213:6, 223:8, 224:13, 226:4, 229:24, 235:5, 237:10, 237:23, 238:23, 239:1, 241:2, 246:17, 246:18, 253:18, 253:21, 253:24, 254:1, 254:4, 254:16, 255:18, 255:19, 255:21, 255:22, 256:5, 256:9, 256:13, 257:10, 257:15, 259:22, 262:7, 264:16, 265:1, 265:7, 266:19, 266:22 cases [20] - 11:22, 11:25, 12:3, 12:7, 12:8, 35:9, 40:24, 83:2, 85:14, 136:15, 144:11, 146:3, 153:25, 155:11, 162:13, 226:5, 226:9, 237:11, 239:23, 243:10 cash [1] - 19:15 cashing [1] - 19:18 categories [1] - 271:25 causation [8] - 30:24, 31:4, 31:12, 31:17, 32:9, 32:13, 32:15, 111:6 caused [3] - 136:16, 136:22, 158:9 causes [6] - 124:11, 124:12, 185:16, 185:21, 186:3, 208:11 causing [1] - 185:12 CD [1] - 24:6 CDC [5] - 196:24, 197:6, 197:12, 197:23, 199:9 Center [6] - 3:12, 5:11, 64:17, 65:1, 69:10, 204:18</p>	<p>center [8] - 11:10, 48:23, 64:19, 68:5, 68:13, 69:6, 70:13, 95:5 certain [8] - 31:22, 32:5, 33:7, 84:16, 87:2, 122:14, 134:2, 213:9 Certainly [1] - 18:14 certainly [9] - 31:24, 31:25, 32:6, 35:8, 99:6, 99:7, 126:25, 147:3, 234:14 certainty [1] - 113:5 CERTIFICATION [1] - 278:17 certify [1] - 278:20 CFR [2] - 41:16, 202:25 chain [9] - 55:14, 57:2, 135:20, 135:25, 136:16, 136:21, 137:8, 185:23, 193:5 chains [3] - 135:14, 136:3, 137:19 challenge [1] - 31:4 challenged [1] - 43:22 chance [12] - 31:23, 33:14, 173:19, 191:8, 192:19, 214:19, 226:8, 237:20, 238:13, 238:22, 250:4, 256:2 Change [1] - 9:1 change [34] - 19:3, 41:6, 43:5, 54:20, 55:5, 55:6, 55:15, 58:8, 58:11, 58:16, 58:19, 60:2, 60:6, 62:21, 75:11, 94:17, 241:17, 241:20, 241:23, 243:5, 244:20, 245:10, 250:23, 252:19, 253:15, 257:5, 257:6, 257:17, 257:18, 258:4, 258:10, 273:23, 276:1 changed [5] - 61:13, 74:17, 104:21, 265:9, 276:4 changes [16] - 9:14, 54:7, 54:8, 54:9, 56:20, 57:1, 207:5, 241:9, 241:13, 241:20, 247:21, 257:21, 275:8, 275:17, 276:22 changing [1] - 245:14</p>	<p>channels [1] - 29:11 characterization [2] - 76:23, 76:24 characterize [2] - 75:13, 147:6 characterizing [2] - 261:1, 261:20 charge [2] - 50:11, 256:3 charged [4] - 137:25, 249:1, 249:13, 249:17 charges [1] - 151:12 CHARLES [1] - 3:11 CHARLESTON [2] - 1:2, 1:18 Charleston [6] - 2:8, 3:13, 4:19, 5:15, 6:9, 7:4 chart [11] - 76:24, 87:21, 89:13, 92:5, 93:20, 125:10, 134:15, 175:18, 194:4, 196:2, 275:16 charts [4] - 154:7, 175:15, 242:10, 242:17 Chase [1] - 4:18 chasm [1] - 226:19 Chateau [1] - 152:16 check [5] - 20:6, 148:25, 170:23, 170:25, 212:10 checkers [1] - 95:14 Chemical [2] - 38:15, 38:18 chemicals [4] - 38:13, 38:19, 38:20 Chesterbrook [1] - 6:15 Chief [1] - 175:4 chief [13] - 11:15, 12:16, 12:22, 21:3, 21:25, 26:11, 29:12, 38:25, 168:6, 253:21, 256:5, 256:10, 259:22 choices [3] - 213:9, 213:12, 213:15 Chris [1] - 263:10 Christmas [1] - 86:11 chronology [1] - 24:6 Chuck [1] - 182:25 cigarettes [1] - 18:24 Cincinnati [1] - 22:7 circle [2] - 17:10, 81:1 Circuit [2] - 266:25, 267:13 circulate [2] - 8:15, 8:16</p>
--	--	--	--	---

<p>circulated [1] - 42:2</p> <p>circumstances [5] - 76:11, 115:3, 130:6, 204:13, 257:22</p> <p>circumvent [1] - 170:3</p> <p>citation [1] - 268:7</p> <p>cite [3] - 125:21, 266:25, 268:9</p> <p>cited [5] - 126:4, 140:15, 266:19, 268:16, 268:20</p> <p>cities [1] - 223:25</p> <p>citing [3] - 126:13</p> <p>citizens [2] - 156:2, 180:23</p> <p>City [11] - 4:1, 5:11, 11:7, 42:12, 56:4, 56:14, 57:18, 59:9, 179:4, 208:22, 278:21</p> <p>CITY [1] - 1:4</p> <p>city [2] - 11:10, 151:6</p> <p>Civil [3] - 1:4, 278:23, 278:24</p> <p>civil [2] - 1:10, 265:1</p> <p>claim [1] - 216:15</p> <p>claimed [1] - 214:10</p> <p>claims [1] - 268:6</p> <p>clarification [6] - 35:7, 88:25, 167:4, 168:25, 214:17, 240:9</p> <p>clarify [2] - 62:16, 78:20</p> <p>clarity [1] - 110:1</p> <p>class [1] - 180:9</p> <p>classifications [2] - 17:12, 17:15</p> <p>clause [1] - 180:5</p> <p>clean [1] - 8:5</p> <p>clean-up [1] - 8:5</p> <p>clear [23] - 24:12, 31:20, 36:17, 43:13, 59:10, 62:11, 62:19, 68:11, 76:18, 79:3, 80:1, 81:5, 83:22, 88:24, 94:11, 97:11, 97:13, 217:19, 234:24, 244:19, 261:16, 276:13</p> <p>cleared [3] - 79:5, 79:18, 228:25</p> <p>clearly [1] - 111:4</p> <p>Cleckley [1] - 263:21</p> <p>CLERK [5] - 7:23, 8:19, 10:5, 10:8, 10:10</p> <p>clerks [1] - 170:22</p> <p>click [1] - 232:5</p> <p>clients [1] - 224:4</p>	<p>clinic [3] - 20:4, 129:21, 129:24</p> <p>clip [2] - 164:22, 165:2</p> <p>close [5] - 23:7, 26:15, 209:23, 233:11, 239:21</p> <p>closed [7] - 16:19, 16:20, 17:11, 133:15, 155:17, 205:2, 270:11</p> <p>closer [1] - 274:14</p> <p>closes [1] - 205:2</p> <p>cocaine [2] - 11:20, 12:7</p> <p>Cochran [3] - 6:17, 278:18, 279:2</p> <p>Code [1] - 37:5</p> <p>code [8] - 83:6, 210:22, 210:25, 212:14, 213:16, 220:18, 220:21</p> <p>coincided [1] - 11:19</p> <p>collaborating [1] - 37:24</p> <p>colleague [1] - 260:7</p> <p>colleagues [8] - 172:11, 174:3, 223:1, 255:21, 259:8, 260:2, 260:5</p> <p>collective [1] - 107:16</p> <p>column [8] - 47:25, 48:1, 48:23, 48:25, 69:12, 120:14, 139:12, 139:13</p> <p>combat [2] - 123:3, 185:2</p> <p>combination [2] - 19:20, 71:4</p> <p>combinations [1] - 19:1</p> <p>combined [1] - 180:12</p> <p>coming [8] - 126:6, 194:10, 205:3, 212:14, 213:16, 222:25, 239:22, 249:14</p> <p>command [1] - 12:20</p> <p>comment [6] - 126:10, 205:15, 221:2, 233:18, 234:1, 261:13</p> <p>comments [4] - 13:11, 14:6, 39:19, 261:5</p> <p>COMMISSION [1] - 1:10</p> <p>Commission [2] - 2:2, 3:2</p> <p>committee [1] - 38:7</p> <p>common [3] - 19:21, 74:22, 149:20</p>	<p>commonly [2] - 76:9, 114:25</p> <p>communicate [2] - 45:5, 67:1</p> <p>communicated [2] - 96:6, 179:15</p> <p>communications [3] - 28:14, 37:25, 42:21</p> <p>community [3] - 12:13, 122:23, 242:3</p> <p>companies [17] - 28:5, 30:1, 42:15, 42:16, 58:10, 60:4, 61:8, 61:9, 116:4, 145:22, 145:23, 146:2, 155:15, 186:14, 251:21, 267:23</p> <p>Company [1] - 45:10</p> <p>company [19] - 24:16, 26:14, 26:16, 27:17, 54:9, 56:20, 75:19, 76:6, 76:12, 82:22, 92:21, 140:11, 146:17, 151:13, 225:10, 236:7, 251:4, 252:1, 276:10</p> <p>compare [1] - 176:25</p> <p>competent [1] - 170:22</p> <p>compilation [2] - 42:5, 42:22</p> <p>compiled [3] - 35:20, 200:6, 201:6</p> <p>complete [7] - 26:8, 26:21, 29:11, 154:20, 272:16, 272:17</p> <p>completely [1] - 86:16</p> <p>completion [1] - 15:14</p> <p>complex [1] - 11:18</p> <p>Compliance [1] - 41:3</p> <p>compliance [6] - 20:21, 258:5, 258:11, 276:23, 276:24, 276:25</p> <p>complicated [1] - 68:24</p> <p>comply [1] - 151:15</p> <p>complying [1] - 134:22</p> <p>component [1] - 44:8</p> <p>compound [3] - 63:6, 209:5, 272:8</p> <p>compounders [2] - 272:11, 272:13</p> <p>compounding [1] - 271:21</p> <p>computer [11] - 6:19, 75:13, 77:17, 83:6, 96:5, 115:1, 210:22,</p>	<p>211:2, 212:25, 213:13</p> <p>concept [3] - 14:11, 196:6, 263:20</p> <p>concern [10] - 51:19, 91:19, 158:9, 183:19, 184:10, 184:12, 184:16, 238:22, 258:5, 258:10</p> <p>concerned [1] - 257:22</p> <p>concerning [1] - 8:25</p> <p>concerns [10] - 9:11, 142:10, 159:22, 169:23, 178:13, 178:16, 178:17, 182:12, 212:6, 212:7</p> <p>concise [1] - 115:19</p> <p>concluded [1] - 165:2</p> <p>concluding [2] - 22:5, 184:24</p> <p>conclusion [7] - 107:12, 108:8, 109:22, 111:4, 185:6, 202:4, 204:25</p> <p>conclusions [2] - 30:14, 147:16</p> <p>condition [1] - 154:13</p> <p>conditionally [4] - 37:15, 43:15, 43:23, 44:1</p> <p>conditions [1] - 142:12</p> <p>conduct [22] - 16:9, 20:18, 26:13, 26:15, 26:20, 32:5, 76:17, 94:11, 106:18, 128:1, 128:22, 145:20, 146:4, 151:4, 152:19, 170:11, 185:24, 188:18, 227:6, 247:13, 250:18, 258:15</p> <p>conducted [15] - 20:24, 23:11, 79:23, 106:4, 106:7, 127:23, 141:20, 141:22, 150:22, 174:18, 226:9, 236:16, 245:25, 250:11, 250:20</p> <p>conducting [4] - 161:11, 161:14, 258:22, 276:17</p> <p>conducts [1] - 168:7</p> <p>confer [2] - 113:8, 190:20</p> <p>conference [8] - 38:7,</p>	<p>263:2, 263:4, 263:7, 263:9, 263:11, 263:14, 263:24</p> <p>Conference [1] - 260:14</p> <p>confidential [1] - 16:8</p> <p>confirm [8] - 26:12, 86:17, 173:23, 174:4, 212:20, 213:5, 233:13</p> <p>confirmed [3] - 39:2, 148:5, 201:17</p> <p>confused [1] - 189:23</p> <p>confusion [2] - 258:5, 258:11</p> <p>Congress [5] - 121:22, 122:5, 178:17, 248:25, 249:13</p> <p>connection [4] - 9:13, 21:15, 124:8, 246:5</p> <p>Connolly [2] - 4:13, 5:4</p> <p>CONROY [1] - 3:3</p> <p>consequences [2] - 183:19, 184:6</p> <p>consider [2] - 127:2, 228:2</p> <p>considerable [2] - 151:6, 186:16</p> <p>consideration [3] - 68:10, 83:25, 220:5</p> <p>consistent [5] - 9:4, 53:18, 147:17, 257:9, 257:14</p> <p>Consolidated [1] - 174:24</p> <p>constantly [1] - 245:14</p> <p>construing [1] - 39:18</p> <p>contact [4] - 11:25, 17:18, 20:21, 122:20</p> <p>contain [1] - 71:8</p> <p>contained [3] - 54:7, 70:1, 255:7</p> <p>contains [1] - 71:3</p> <p>context [2] - 249:2, 253:17</p> <p>continue [13] - 24:19, 25:25, 26:5, 48:22, 72:19, 93:11, 94:12, 98:25, 111:14, 154:15, 234:16, 239:4, 239:14</p> <p>Continued [5] - 3:1, 5:1, 5:6, 6:1, 6:10</p> <p>continued [2] - 24:25, 235:7</p> <p>continues [2] - 226:23, 264:12</p>
---	---	---	--	---

<p>continuing [4] - 46:12, 73:23, 112:17, 259:12</p> <p>contract [2] - 55:5, 55:14</p> <p>contradicts [1] - 65:11</p> <p>contrary [1] - 147:7</p> <p>contributed [6] - 139:19, 139:24, 143:10, 143:14, 143:19, 186:14</p> <p>contributing [3] - 125:11, 125:16, 126:15</p> <p>control [12] - 30:10, 30:11, 107:4, 107:22, 108:4, 108:16, 110:7, 182:5, 196:23, 198:20, 270:4, 270:11</p> <p>Control [6] - 50:11, 54:21, 121:11, 123:7, 163:12, 192:9</p> <p>controlled [34] - 16:16, 17:4, 21:13, 22:24, 27:15, 28:16, 29:1, 30:2, 30:6, 30:12, 38:19, 38:21, 42:13, 44:12, 48:14, 55:16, 75:10, 104:5, 107:10, 117:2, 120:16, 120:24, 121:5, 134:18, 136:9, 142:24, 143:3, 155:20, 156:22, 180:10, 183:1, 185:2, 236:2, 272:11</p> <p>Controlled [1] - 118:22</p> <p>controls [11] - 23:20, 24:13, 28:25, 30:1, 32:12, 76:5, 107:9, 146:7, 233:8, 246:25, 251:19</p> <p>conversation [8] - 160:10, 160:13, 211:6, 212:6, 212:8, 212:16, 212:17, 222:18</p> <p>conversations [1] - 215:18</p> <p>Cook [3] - 6:18, 278:19, 279:2</p> <p>cooperative [1] - 28:8</p> <p>copied [1] - 230:13</p> <p>copies [6] - 7:25, 8:10, 8:17, 13:8, 63:18, 63:24</p>	<p>copy [7] - 13:9, 42:4, 210:21, 244:5, 267:12, 278:7, 278:9</p> <p>corner [15] - 66:19, 67:16, 71:19, 119:2, 120:9, 139:7, 140:7, 142:22, 152:15, 163:16, 163:22, 179:25, 192:13, 197:12, 267:19</p> <p>corporation [4] - 1:7, 1:13, 170:3</p> <p>Corporation [2] - 6:2, 278:23</p> <p>correct [426] - 40:21, 46:8, 54:22, 57:8, 57:13, 57:14, 57:19, 57:20, 58:1, 60:7, 64:13, 66:9, 69:6, 69:7, 69:11, 70:13, 70:14, 70:23, 71:14, 71:18, 71:23, 72:1, 72:2, 72:23, 72:24, 73:1, 73:4, 73:7, 73:12, 74:19, 74:20, 79:17, 79:19, 79:20, 80:12, 81:7, 87:13, 88:6, 88:9, 88:10, 88:14, 88:18, 88:19, 89:19, 95:15, 96:15, 96:16, 97:7, 97:18, 97:22, 97:23, 102:2, 104:10, 105:16, 116:2, 116:3, 116:10, 116:11, 116:24, 117:17, 118:19, 119:6, 121:18, 122:24, 123:21, 124:1, 125:8, 125:9, 127:20, 128:15, 128:24, 129:6, 129:7, 130:24, 131:1, 131:2, 131:4, 131:12, 131:13, 131:16, 131:17, 131:19, 132:15, 132:18, 133:7, 134:5, 134:6, 134:13, 134:23, 134:24, 135:4, 135:5, 135:6, 135:11, 135:16, 135:20, 136:4, 136:7, 136:12, 136:17, 136:22, 136:23, 136:25, 137:16, 137:23, 137:24, 138:3, 138:6, 138:7, 138:9,</p>	<p>138:16, 144:6, 144:7, 144:9, 144:10, 144:13, 144:14, 144:17, 144:25, 145:3, 145:15, 145:21, 145:24, 146:5, 146:9, 146:10, 146:13, 148:14, 148:19, 148:24, 149:1, 149:2, 149:4, 149:5, 149:6, 149:12, 149:13, 150:3, 150:7, 150:24, 150:25, 151:4, 151:15, 153:25, 155:8, 155:13, 155:14, 155:24, 156:4, 156:9, 156:13, 156:14, 157:22, 159:13, 161:18, 161:19, 162:17, 163:4, 166:19, 166:24, 167:14, 167:18, 168:11, 168:12, 168:16, 173:9, 173:12, 173:17, 173:20, 173:25, 174:15, 174:18, 175:1, 175:16, 175:24, 176:4, 176:20, 177:2, 177:5, 177:8, 177:14, 177:17, 178:14, 178:20, 181:5, 183:23, 183:25, 186:11, 188:10, 188:11, 189:11, 191:15, 191:18, 191:20, 191:23, 192:1, 192:20, 192:23, 193:11, 194:18, 194:25, 195:1, 195:4, 195:11, 195:14, 196:1, 196:14, 198:22, 199:25, 200:7, 200:10, 200:12, 201:11, 201:13, 201:14, 201:15, 201:16, 202:8, 202:25, 204:7, 204:9, 204:15, 204:21, 204:23, 204:25, 205:4, 205:10, 206:7, 206:9, 206:10, 206:18, 206:24, 208:1, 208:5, 208:8,</p>	<p>208:11, 208:17, 208:18, 208:20, 209:1, 209:19, 210:18, 210:22, 210:25, 211:5, 211:22, 212:11, 212:14, 212:17, 213:6, 213:22, 213:23, 214:8, 214:14, 214:16, 214:20, 214:21, 214:25, 215:2, 215:3, 215:5, 215:6, 215:10, 216:4, 216:5, 216:9, 216:17, 216:24, 216:25, 217:5, 218:20, 219:11, 219:21, 220:12, 220:17, 222:7, 222:9, 222:12, 222:16, 222:17, 222:19, 222:23, 223:23, 223:25, 224:2, 224:3, 224:18, 224:23, 224:24, 224:25, 225:9, 225:12, 225:17, 225:18, 225:22, 226:1, 226:7, 226:10, 226:17, 226:18, 227:8, 227:9, 227:11, 227:12, 227:15, 228:8, 228:9, 228:14, 229:2, 229:9, 231:12, 231:13, 231:14, 232:2, 232:7, 232:22, 232:23, 232:25, 233:1, 233:2, 233:6, 235:3, 236:9, 236:10, 236:14, 236:15, 236:17, 236:18, 236:21, 236:22, 237:24, 237:25, 238:3, 238:6, 238:20, 238:21, 238:23, 238:24, 239:2, 239:23, 240:1, 240:5, 241:8, 241:11, 241:18, 241:19, 241:21, 241:22, 241:24, 241:25, 242:5, 242:16, 242:17, 242:20, 242:25, 243:1, 244:22, 245:2, 245:3, 245:6,</p>	<p>245:7, 245:15, 246:22, 246:25, 247:5, 248:23, 249:19, 249:23, 250:2, 250:8, 250:11, 251:6, 251:16, 252:3, 252:16, 252:20, 253:1, 253:4, 253:12, 253:22, 254:6, 254:13, 254:20, 254:22, 255:1, 255:7, 255:11, 255:14, 256:6, 257:10, 258:20, 258:23, 258:24, 259:2, 259:18, 259:20, 259:23, 260:11, 262:7, 262:9, 262:12, 262:13, 264:17, 264:22, 266:1, 268:2, 268:3, 268:25, 269:1, 269:4, 269:23, 270:2, 270:13, 271:6, 271:9, 271:16, 271:18, 273:4, 274:22, 275:1, 275:20, 275:22, 275:25, 276:25, 278:20</p> <p>Correct [13] - 117:3, 117:6, 121:16, 133:24, 148:23, 161:23, 162:25, 175:5, 175:21, 176:14, 185:25, 186:5, 194:3</p> <p>correction [2] - 91:6, 251:23</p> <p>correctly [10] - 33:10, 164:9, 169:2, 187:10, 189:6, 229:3, 261:22, 268:7, 269:12, 269:13</p> <p>correlation [2] - 216:10, 216:14</p> <p>corresponding [11] - 131:25, 132:6, 132:14, 132:17, 133:1, 133:5, 135:3, 160:9, 216:8, 216:11, 216:14</p> <p>Correspondingly [1] - 135:8</p> <p>counsel [11] - 13:8, 21:3, 21:25, 26:11, 29:13, 31:6, 31:7,</p>
--	--	---	---	--

<p>34:6, 63:25, 210:20, 222:19</p> <p>counsel's [1] - 39:1</p> <p>count [5] - 18:10, 21:7, 136:11, 206:2, 206:8</p> <p>counties [6] - 17:25, 125:4, 209:1, 209:16, 224:2</p> <p>counting [1] - 21:11</p> <p>country [4] - 16:22, 164:7, 200:4, 201:3</p> <p>county [17] - 56:14, 59:11, 59:12, 144:23, 151:6, 173:12, 173:14, 176:8, 176:9, 176:12, 176:13, 178:25, 179:1, 179:6, 179:10</p> <p>COUNTY [1] - 1:10</p> <p>County [72] - 2:2, 3:2, 9:14, 11:1, 11:6, 42:11, 44:12, 46:20, 46:25, 47:5, 50:2, 54:25, 56:4, 59:4, 59:9, 97:17, 103:5, 106:5, 106:10, 106:14, 106:25, 107:6, 107:24, 108:6, 108:17, 109:3, 110:9, 111:1, 111:21, 112:6, 112:25, 124:8, 124:13, 125:8, 127:16, 127:18, 128:12, 129:5, 129:10, 134:13, 134:21, 135:9, 135:23, 136:1, 144:17, 149:16, 150:23, 153:2, 172:24, 179:5, 179:12, 185:17, 185:21, 186:15, 206:14, 208:21, 208:23, 208:25, 209:8, 209:10, 209:12, 209:14, 210:18, 211:20, 241:24, 242:7, 262:11, 271:2, 271:5, 272:21</p> <p>couple [13] - 9:11, 12:13, 14:6, 18:12, 19:25, 23:15, 23:16, 44:9, 163:2, 163:4, 240:1, 250:1, 250:5</p> <p>course [17] - 21:23, 33:19, 34:19, 37:11,</p>	<p>58:25, 86:20, 90:4, 125:24, 155:5, 156:20, 157:20, 196:22, 227:18, 264:23, 265:9, 265:16, 278:10</p> <p>court [11] - 34:22, 39:18, 43:5, 100:11, 136:19, 137:3, 176:20, 235:12, 236:24, 255:13, 267:6</p> <p>Court [49] - 6:17, 6:18, 7:3, 7:12, 10:21, 13:16, 13:20, 27:5, 30:14, 33:6, 34:20, 34:25, 35:25, 36:5, 37:14, 39:22, 42:7, 43:19, 45:4, 51:25, 54:4, 60:20, 61:24, 63:21, 75:3, 82:6, 100:20, 101:9, 119:16, 125:22, 139:6, 147:2, 202:11, 206:2, 216:4, 224:12, 226:14, 230:7, 239:1, 239:19, 240:24, 256:14, 264:23, 264:25, 265:4, 267:7, 278:18, 278:19</p> <p>COURT [211] - 1:1, 1:17, 7:6, 7:9, 7:13, 7:24, 8:2, 8:11, 8:18, 9:8, 9:19, 9:23, 10:1, 10:14, 14:2, 14:9, 14:13, 21:15, 25:18, 25:23, 26:2, 30:15, 30:25, 31:7, 32:8, 32:18, 32:20, 33:4, 33:9, 33:17, 35:1, 35:11, 35:14, 36:17, 36:22, 39:14, 39:24, 40:3, 40:8, 40:11, 40:16, 43:4, 43:7, 43:12, 44:4, 45:1, 45:24, 46:15, 47:15, 48:3, 48:5, 50:23, 51:7, 51:16, 52:4, 52:8, 52:23, 53:5, 53:9, 53:13, 53:24, 59:21, 60:18, 60:22, 62:7, 62:13, 63:10, 64:2, 64:8, 65:16, 65:22, 65:24, 66:4, 66:21, 68:15, 68:21, 69:17, 69:19, 70:4, 70:9, 72:8, 72:10, 72:11, 72:13, 72:14, 72:15, 72:20, 73:17,</p>	<p>74:3, 74:8, 74:13, 75:4, 77:3, 78:7, 78:15, 79:4, 80:2, 80:7, 80:10, 81:11, 81:14, 82:13, 85:22, 86:12, 86:19, 89:24, 90:2, 90:10, 90:20, 90:23, 91:1, 91:11, 91:17, 91:24, 94:2, 99:7, 99:10, 99:14, 99:18, 100:9, 105:10, 106:19, 107:13, 107:17, 108:20, 109:14, 109:19, 109:24, 110:13, 110:15, 110:21, 111:13, 112:9, 112:13, 112:16, 113:9, 113:13, 113:18, 113:21, 113:25, 115:8, 115:11, 118:11, 119:12, 119:14, 119:24, 120:2, 126:23, 127:2, 127:14, 128:7, 138:20, 138:22, 145:6, 145:9, 147:14, 154:22, 160:22, 160:25, 165:14, 166:1, 166:4, 172:16, 172:19, 174:9, 174:21, 178:1, 187:14, 187:21, 189:17, 189:23, 190:10, 190:18, 190:22, 192:5, 192:7, 193:3, 197:20, 198:2, 198:24, 199:2, 199:5, 202:18, 202:22, 203:2, 207:13, 207:19, 209:6, 214:3, 215:21, 215:24, 217:23, 221:18, 221:24, 233:20, 234:7, 234:17, 239:8, 256:17, 262:16, 262:20, 262:22, 263:17, 263:25, 270:19, 277:9, 277:19, 277:23, 278:1, 278:11, 278:13</p> <p>Court's [3] - 16:2, 30:18, 265:18</p> <p>courtesy [1] - 31:6</p> <p>cover [7] - 17:23, 17:25, 49:16, 67:13,</p>	<p>124:23, 138:25, 160:4</p> <p>covered [4] - 45:17, 64:25, 185:11, 230:25</p> <p>covering [2] - 124:8, 190:7</p> <p>covers [5] - 61:19, 125:3, 125:8, 193:13, 193:14</p> <p>Covington [1] - 5:11</p> <p>crack [2] - 11:20, 120:17</p> <p>crack-down [1] - 120:17</p> <p>crate [1] - 48:16</p> <p>create [4] - 68:4, 68:6, 92:9, 223:6</p> <p>created [6] - 166:16, 166:23, 222:11, 222:14, 223:9, 223:13</p> <p>creates [2] - 88:10, 88:11</p> <p>creating [1] - 54:4</p> <p>crime [1] - 11:18</p> <p>crimes [4] - 195:3, 195:21</p> <p>criminal [7] - 151:12, 162:9, 170:10, 170:19, 195:17, 265:5, 265:11</p> <p>crisis [15] - 122:24, 123:1, 123:19, 124:12, 136:16, 136:22, 137:15, 137:20, 144:13, 185:8, 185:12, 185:16, 185:21, 186:3, 186:14</p> <p>criteria [3] - 66:10, 66:11, 180:22</p> <p>critical [1] - 83:3</p> <p>criticism [9] - 177:14, 185:10, 223:15, 227:3, 237:4, 237:13, 237:16, 237:17, 249:21</p> <p>criticized [4] - 177:12, 181:6, 191:2, 191:6</p> <p>critique [1] - 226:9</p> <p>critiques [2] - 240:4, 240:14</p> <p>CROSS [1] - 115:12</p> <p>cross [16] - 30:20, 52:3, 63:12, 74:12, 77:4, 77:5, 78:5, 79:5, 99:6, 109:23, 115:8, 119:20, 147:15, 154:23,</p>	<p>172:19, 263:25</p> <p>cross-examination [4] - 30:20, 147:15, 154:23, 172:19</p> <p>cross-examine [1] - 115:8</p> <p>cross-examined [1] - 52:3</p> <p>crowds [1] - 18:22</p> <p>CRR [2] - 6:17, 6:18</p> <p>CSA [3] - 41:16, 120:16, 151:15</p> <p>CSMP [2] - 275:1, 275:4</p> <p>cue [1] - 90:24</p> <p>cull [26] - 120:14, 140:25, 146:20, 152:6, 157:11, 164:15, 164:16, 169:19, 181:9, 186:18, 188:22, 200:22, 202:16, 202:21, 211:23, 212:21, 224:22, 228:21, 235:10, 256:19, 256:25, 261:17, 264:8, 267:3, 267:18</p> <p>culled [1] - 143:9</p> <p>cumulative [1] - 154:11</p> <p>current [1] - 148:4</p> <p>custodial [1] - 15:12</p> <p>customer [30] - 23:12, 23:16, 23:17, 23:23, 24:8, 24:12, 26:18, 28:9, 42:19, 67:3, 67:5, 67:7, 70:18, 70:20, 71:21, 76:16, 78:12, 83:4, 92:19, 94:2, 94:15, 95:15, 102:10, 130:13, 130:22, 149:20, 235:25, 236:2, 257:23</p> <p>customers [7] - 24:7, 70:18, 72:7, 84:11, 106:25, 205:3, 271:20</p> <p>cut [6] - 53:13, 91:14, 149:25, 150:1, 150:5, 183:17</p> <p>cuts [1] - 149:20</p> <p>cutting [2] - 183:14, 183:18</p> <p>Cuyahoga [5] - 208:23, 209:8, 210:18, 211:20, 262:11</p> <p>CVS [1] - 136:4</p>
---	---	--	---	---

D				
D.C [2] - 29:13, 167:10 DADS [1] - 201:1 daily [6] - 61:9, 95:11, 95:12, 101:8, 274:4 dark [2] - 56:10, 56:23 Data [1] - 192:10 data [90] - 13:15, 23:12, 26:6, 26:19, 27:14, 28:23, 42:12, 44:9, 44:11, 44:16, 44:19, 45:8, 45:11, 45:14, 45:15, 45:16, 45:22, 45:23, 46:6, 46:21, 47:1, 47:6, 47:22, 50:3, 50:8, 50:13, 52:1, 53:1, 53:15, 53:17, 57:7, 57:12, 57:15, 59:5, 61:10, 61:11, 61:15, 61:16, 61:18, 61:21, 62:6, 65:7, 82:3, 84:22, 95:24, 96:11, 100:21, 104:16, 115:2, 125:21, 126:4, 126:7, 126:11, 140:11, 140:18, 149:4, 150:13, 151:25, 152:2, 173:7, 173:11, 175:16, 175:20, 175:21, 176:7, 176:19, 177:5, 178:6, 191:2, 191:4, 191:7, 191:11, 191:12, 191:14, 200:3, 201:2, 201:6, 201:21, 202:4, 236:9, 245:19, 246:22, 247:8, 271:10, 271:19, 272:7, 272:18, 275:7, 275:8 database [18] - 73:6, 114:6, 114:11, 114:21, 166:13, 166:15, 166:18, 166:19, 166:22, 167:1, 167:5, 167:12, 167:14, 173:25, 174:25, 177:7, 199:25, 201:19 datasets [2] - 87:2, 87:4 Date [1] - 279:7 date [5] - 67:9, 197:22, 197:24, 228:11	dated [5] - 8:16, 118:15, 211:13, 211:15, 268:23 Dated [1] - 148:1 dates [2] - 45:22, 269:2 Daubert [2] - 30:17, 43:18 David [1] - 7:1 DAVID [2] - 1:17, 2:9 DC [8] - 2:11, 4:7, 4:14, 4:16, 5:5, 5:12, 85:5, 236:24 De [2] - 2:4, 2:16 DEA [222] - 11:25, 12:3, 12:4, 12:5, 12:6, 13:1, 15:1, 15:3, 15:9, 15:11, 15:19, 16:13, 16:15, 17:14, 21:3, 21:25, 23:1, 25:17, 26:24, 28:18, 29:12, 29:16, 29:21, 36:11, 36:16, 37:22, 38:2, 38:15, 38:17, 38:24, 39:1, 39:9, 40:20, 40:25, 41:14, 42:23, 61:4, 61:8, 64:12, 64:23, 64:24, 65:9, 66:8, 72:3, 73:11, 73:16, 76:20, 83:11, 103:7, 114:25, 116:25, 117:6, 117:8, 118:3, 118:8, 118:25, 119:4, 119:18, 120:17, 120:22, 121:10, 121:20, 122:4, 122:5, 122:18, 123:4, 123:5, 123:7, 123:21, 123:22, 123:23, 123:25, 124:2, 124:11, 124:23, 126:6, 126:12, 126:13, 128:19, 131:14, 131:22, 131:24, 131:25, 133:6, 133:12, 141:7, 142:7, 142:10, 143:1, 143:17, 144:5, 144:9, 150:5, 150:8, 155:16, 155:17, 156:3, 156:5, 156:15, 156:21, 157:21, 158:4, 158:8, 158:12, 158:16, 158:18, 159:10, 159:11, 159:14,	159:16, 160:1, 161:9, 162:6, 162:12, 162:16, 164:5, 164:12, 164:24, 166:14, 167:11, 167:22, 168:7, 170:4, 170:11, 171:23, 172:1, 172:12, 173:7, 173:23, 173:24, 175:19, 176:1, 176:6, 176:19, 177:4, 178:1, 178:20, 178:25, 179:4, 179:10, 180:10, 180:23, 181:3, 181:15, 182:25, 183:12, 183:25, 184:10, 184:24, 185:14, 187:7, 191:1, 199:25, 200:3, 200:6, 201:2, 201:6, 201:11, 201:25, 202:8, 202:15, 203:13, 203:16, 206:12, 206:18, 206:23, 208:11, 222:5, 222:9, 223:2, 223:19, 225:6, 229:9, 229:16, 230:1, 233:11, 236:16, 236:20, 245:11, 245:14, 245:18, 245:20, 246:8, 248:17, 249:1, 249:14, 249:21, 250:11, 250:16, 250:20, 251:6, 251:9, 251:14, 252:1, 252:15, 253:10, 254:8, 255:11, 257:4, 257:21, 258:5, 258:11, 258:15, 259:8, 259:10, 259:18, 260:5, 260:6, 260:10, 261:6, 261:12, 264:20, 266:23, 268:4, 268:10, 269:9, 269:19 DEA's [13] - 115:1, 124:3, 124:7, 142:24, 166:18, 168:6, 174:5, 182:7, 199:25, 201:19, 250:6, 260:13, 260:14	deal [2] - 13:18, 28:15 dealt [1] - 21:5 death [1] - 181:12 December [2] - 15:17, 138:12 decide [2] - 43:16, 119:20 decided [1] - 267:13 decision [32] - 12:19, 29:9, 29:13, 33:15, 75:15, 76:7, 76:9, 76:13, 83:3, 93:25, 122:8, 159:20, 160:11, 182:17, 184:9, 225:16, 239:12, 242:7, 255:13, 255:16, 256:18, 265:1, 266:4, 266:14, 266:18, 267:3, 267:6, 267:12, 267:17, 268:12, 269:2, 269:3 decision-making [1] - 182:17 decisions [11] - 31:21, 39:18, 117:20, 172:6, 182:10, 188:6, 191:9, 224:5, 224:7, 249:15, 270:5 deck [1] - 238:9 decline [2] - 55:4, 55:12 decrease [1] - 55:18 deemed [1] - 51:11 deems [1] - 180:11 DEF [1] - 202:14 DEF-WV [1] - 202:14 DEF-WV-1597 [1] - 179:22 DEF-WV-2661 [1] - 256:8 DEF-WV-3532 [1] - 267:4 Defendant [4] - 4:10, 5:2, 5:7, 6:2 defendant [4] - 47:4, 50:2, 50:7, 146:8 Defendants [3] - 1:8, 1:14, 278:23 defendants [67] - 29:24, 33:12, 36:15, 37:2, 38:11, 39:19, 42:18, 42:19, 44:11, 46:24, 47:21, 50:12, 50:15, 57:11, 59:2, 59:14, 60:9, 62:20, 62:21, 64:12, 65:3, 65:5, 73:14, 74:23, 77:11, 77:22, 78:11,	80:4, 83:7, 87:4, 95:24, 97:8, 100:21, 102:20, 104:16, 112:4, 112:18, 112:23, 116:2, 116:6, 116:12, 129:15, 132:25, 134:15, 134:18, 136:12, 146:5, 147:3, 147:5, 147:11, 154:11, 154:13, 155:10, 174:2, 202:4, 206:4, 206:22, 210:7, 223:11, 228:10, 228:25, 240:17, 241:3, 253:7 defendants' [3] - 61:25, 95:20, 96:11 Defendants' [8] - 118:14, 119:11, 124:22, 126:20, 162:23, 163:9, 173:17, 190:16 defense [1] - 133:7 Defense [2] - 191:17, 192:3 defer [1] - 43:19 define [2] - 200:16, 204:11 defines [1] - 203:4 definitely [1] - 37:24 definition [8] - 18:21, 187:7, 187:8, 202:10, 203:8, 203:24, 205:14 definitive [4] - 144:20, 187:18, 229:1, 254:9 degree [1] - 113:4 delineate [1] - 54:15 delineated [1] - 180:21 delivered [1] - 64:22 Demo223_0003 [1] - 34:20 Demo223_4 [1] - 36:8 demographic [1] - 241:20 demonstrative [21] - 13:6, 34:22, 35:1, 42:3, 51:6, 63:21, 99:4, 99:8, 99:9, 152:7, 200:20, 232:12, 232:13, 238:9, 244:5, 265:22, 265:24, 270:23, 278:5, 278:8 Demonstrative [1] - 230:22 demonstratives [2] -

<p>86:3, 218:23 denied [1] - 172:12 dentists [4] - 17:7, 168:20, 169:4, 171:7 deny [3] - 107:17, 166:4, 191:7 denying [1] - 191:7 Department [5] - 11:1, 11:3, 11:6, 11:7, 118:21 department [3] - 11:18, 12:9, 12:19 depicting [1] - 50:16 depiction [2] - 56:13, 96:10 depicts [2] - 44:18, 60:12 depose [1] - 238:5 deposed [1] - 253:24 Deposition [1] - 148:4 deposition [16] - 136:20, 165:4, 173:20, 173:23, 174:17, 192:23, 213:21, 238:23, 239:22, 239:25, 254:3, 257:13, 257:14, 257:16, 262:4, 262:14 depositions [6] - 36:13, 42:17, 226:11, 226:12, 237:15, 240:4 deprive [2] - 183:14, 184:14 deprived [3] - 217:7, 218:4, 218:8 depriving [1] - 184:7 depth [1] - 94:16 deputy [1] - 12:16 describe [7] - 9:3, 41:17, 47:17, 61:23, 69:23, 75:2, 82:18 described [3] - 78:23, 89:13, 166:13 describes [1] - 93:24 describing [1] - 62:19 description [4] - 9:2, 27:24, 27:25, 93:15 descriptions [1] - 17:16 design [9] - 74:21, 74:22, 76:1, 84:10, 88:20, 213:9, 213:13, 213:15, 225:11 designation [1] - 15:25 designed [13] - 29:3, 30:4, 37:19, 79:14,</p>	<p>80:6, 80:8, 80:12, 83:18, 83:20, 88:15, 97:13, 109:1, 233:14 designing [2] - 84:12, 84:13 desire [2] - 84:10, 128:8 despite [1] - 143:17 destined [1] - 260:18 detail [2] - 77:8, 124:4 detailed [1] - 26:21 detect [2] - 24:23, 185:2 detective [1] - 11:14 determination [7] - 28:24, 29:7, 43:19, 43:23, 82:21, 117:18 determine [14] - 27:19, 67:22, 70:16, 79:15, 83:3, 95:18, 117:16, 117:20, 172:12, 173:7, 173:11, 176:13, 179:1, 206:20 determined [4] - 20:9, 95:20, 141:8, 228:14 determining [2] - 70:6, 116:16 Detroit [18] - 11:2, 11:4, 11:8, 11:9, 11:21, 15:16, 17:23, 18:4, 18:15, 20:3, 20:6, 20:7, 164:14, 165:8, 165:12, 165:20, 170:21, 171:7 develop [1] - 251:2 developing [1] - 200:9 development [2] - 241:10, 241:13 deviating [2] - 82:25, 203:6 devoted [1] - 276:25 diagram [5] - 60:12, 74:21, 192:13, 192:16, 195:21 difference [12] - 36:18, 41:4, 89:10, 109:15, 189:17, 219:18, 219:19, 219:25, 226:24, 227:4, 230:5, 238:19 different [40] - 9:17, 14:7, 16:3, 16:18, 16:23, 17:7, 56:20, 62:24, 65:3, 76:23, 81:3, 83:22, 84:7, 84:21, 87:1, 98:12, 135:10, 145:25, 175:16, 179:13,</p>	<p>185:11, 186:22, 193:9, 193:11, 198:16, 219:5, 220:11, 225:23, 226:12, 226:25, 229:17, 237:18, 239:13, 243:3, 244:15, 245:9, 248:13, 249:7, 250:21, 271:8 differently [2] - 85:10, 146:1 differs [2] - 225:25, 226:21 difficult [2] - 122:8, 182:16 dig [1] - 227:1 diligence [50] - 23:18, 42:20, 76:10, 77:21, 77:24, 79:23, 81:6, 88:24, 89:4, 89:18, 89:22, 94:11, 97:9, 102:1, 102:3, 102:5, 106:4, 106:8, 109:16, 204:24, 217:13, 217:17, 220:6, 226:17, 227:4, 227:7, 228:4, 228:18, 229:10, 229:12, 233:10, 234:24, 235:1, 235:6, 236:8, 236:13, 237:22, 243:3, 244:19, 244:23, 245:25, 264:19, 267:23, 269:22, 269:25, 270:13, 270:14, 276:17, 276:22 diminish [1] - 183:16 ding [9] - 80:16, 80:20, 80:22 DIRECT [1] - 10:15 direct [8] - 115:17, 124:17, 146:15, 150:17, 157:2, 161:8, 210:5, 217:2 directed [2] - 134:8, 198:18 directly [14] - 38:21, 39:2, 52:16, 65:11, 146:14, 149:15, 152:3, 159:25, 160:12, 165:10, 187:14, 211:9, 221:14, 244:2 disagree [13] - 120:25, 122:7, 122:12, 122:16, 122:17, 137:10, 140:1,</p>	<p>140:3, 169:14, 205:7, 233:21, 244:11, 259:23 disappoint [1] - 240:7 disaster [1] - 219:1 discern [2] - 77:10, 83:19 disclose [2] - 162:6, 170:10 disclosed [5] - 35:20, 52:21, 85:21, 102:19, 111:10 disclosure [1] - 178:2 discovered [3] - 104:22, 202:9, 223:8 discovery [3] - 35:16, 42:11, 254:21 discretion [1] - 43:21 discuss [6] - 27:22, 160:8, 174:6, 211:2, 212:25, 238:13 discussed [9] - 85:5, 137:10, 163:1, 182:11, 211:7, 211:8, 213:18, 237:15, 252:17 discusses [1] - 143:1 discussing [7] - 28:1, 155:22, 180:3, 227:2, 249:16, 257:12, 266:3 discussion [9] - 23:11, 46:4, 126:12, 142:24, 143:17, 212:15, 212:24, 261:10 discussions [6] - 160:14, 160:15, 160:16, 160:18, 211:8, 251:18 dispel [5] - 76:18, 79:24, 102:15, 104:10, 217:14 dispelled [4] - 76:14, 97:12, 104:12, 229:11 dispels [1] - 76:15 dispense [5] - 131:11, 133:17, 133:21, 148:14, 156:12 dispensed [6] - 131:8, 132:25, 134:11, 135:3, 198:20, 242:13 dispensers [2] - 273:4, 273:7 dispenses [1] - 134:7 dispensing [3] - 117:1, 122:21, 272:11</p>	<p>Dispensing [1] - 118:22 display [1] - 271:19 dispute [4] - 133:11, 150:17, 181:24, 212:5 disputing [1] - 252:10 disruption [1] - 112:11 distinction [2] - 32:15, 79:3 distinguish [1] - 61:16 distribute [6] - 135:21, 136:6, 158:6, 159:12, 162:13 distributed [15] - 39:9, 46:24, 47:4, 48:24, 49:2, 50:2, 59:4, 63:18, 87:23, 134:5, 154:4, 178:10, 207:25, 208:4, 217:16 distributes [1] - 136:1 distributing [5] - 19:18, 84:1, 84:3, 135:15, 151:5 Distribution [3] - 64:17, 64:25, 69:10 distribution [42] - 19:9, 22:24, 23:4, 27:15, 28:16, 30:6, 39:6, 42:13, 44:11, 45:8, 48:1, 55:19, 56:22, 61:6, 64:19, 68:4, 68:5, 68:13, 69:6, 70:13, 72:6, 87:12, 88:2, 88:22, 92:15, 94:19, 95:4, 106:13, 130:16, 130:17, 137:6, 143:3, 155:17, 176:2, 176:7, 179:6, 179:11, 179:12, 200:11, 242:16, 243:22, 272:6 distributions [2] - 59:8, 153:17 distributor [52] - 21:10, 22:3, 39:6, 40:21, 46:20, 48:7, 48:11, 55:15, 56:6, 57:1, 60:25, 61:1, 61:2, 61:7, 62:4, 68:10, 75:10, 77:16, 143:4, 148:21, 149:20, 149:21, 150:1, 150:3, 151:3, 153:24, 160:12, 161:10, 179:5, 179:16, 204:25,</p>
---	---	---	--	---

<p>210:8, 225:10, 235:22, 244:20, 246:7, 252:23, 253:2, 253:5, 253:6, 254:6, 254:15, 254:25, 255:11, 257:22, 258:15, 258:19, 258:23, 259:3, 265:4, 265:10, 269:18</p> <p>distributor's [1] - 179:12</p> <p>distributors [87] - 17:2, 17:3, 19:23, 20:6, 20:7, 35:5, 37:17, 40:25, 55:6, 74:17, 94:25, 116:9, 117:8, 117:15, 117:19, 126:16, 132:18, 135:15, 143:18, 143:23, 145:23, 148:12, 148:17, 149:10, 149:15, 149:19, 150:10, 150:14, 150:22, 151:2, 154:15, 155:23, 158:5, 158:13, 158:18, 161:6, 162:13, 164:3, 168:11, 173:8, 173:12, 177:4, 177:8, 177:10, 177:11, 177:12, 177:15, 177:19, 178:5, 179:9, 184:12, 185:13, 186:7, 186:10, 186:25, 191:2, 191:8, 191:14, 194:5, 194:9, 194:10, 194:17, 194:18, 194:21, 194:24, 195:25, 198:20, 199:22, 199:24, 201:18, 202:7, 220:12, 224:6, 227:6, 232:7, 236:14, 245:18, 245:21, 246:3, 253:11, 254:4, 254:12, 260:13, 260:16, 269:10, 269:16</p> <p>Distributors [2] - 148:12, 193:16</p> <p>District [2] - 7:2, 7:3</p> <p>DISTRICT [3] - 1:1, 1:1, 1:17</p> <p>Diversion [7] - 16:1,</p>	<p>50:11, 54:20, 121:11, 123:7, 138:14, 163:12</p> <p>diversion [110] - 15:7, 16:3, 16:10, 23:21, 24:14, 29:1, 30:2, 30:9, 30:11, 32:12, 76:5, 76:15, 79:24, 84:18, 94:12, 97:12, 104:3, 104:4, 104:12, 107:5, 107:10, 107:22, 108:4, 108:16, 110:8, 110:25, 111:20, 114:25, 128:14, 129:12, 129:16, 133:7, 135:11, 139:19, 139:24, 141:8, 143:10, 143:14, 143:19, 146:7, 151:15, 152:19, 153:1, 153:18, 153:19, 156:16, 166:13, 171:18, 172:9, 177:22, 177:25, 182:5, 183:17, 183:22, 184:8, 185:2, 187:7, 191:12, 193:6, 193:10, 193:11, 194:1, 194:2, 194:10, 194:17, 195:13, 195:18, 196:4, 196:6, 196:22, 196:23, 196:24, 196:25, 203:25, 204:2, 204:6, 205:10, 208:1, 208:4, 208:8, 208:11, 217:12, 217:14, 217:18, 217:20, 223:3, 233:9, 236:17, 236:21, 248:10, 248:18, 248:19, 249:2, 249:14, 249:19, 250:7, 250:10, 250:19, 250:20, 251:19, 253:16, 254:24, 255:4, 255:23, 269:12, 269:17, 270:4, 272:4</p> <p>diverted [19] - 24:23, 30:7, 76:3, 79:19, 79:22, 81:7, 104:8, 112:5, 112:24, 153:14, 204:14, 204:23, 205:14, 205:20, 214:11,</p>	<p>216:15, 222:22, 243:6, 243:10</p> <p>diverters [2] - 186:25, 187:6</p> <p>division [5] - 12:17, 164:5, 166:14, 167:11, 169:22</p> <p>divisional [2] - 15:17, 170:21</p> <p>dixit [1] - 147:13</p> <p>do-over [1] - 53:4</p> <p>doctor [18] - 17:6, 18:7, 18:18, 18:23, 19:8, 19:10, 128:12, 128:16, 129:10, 129:11, 130:10, 130:19, 132:1, 149:15, 157:17, 195:7, 218:11, 222:3</p> <p>doctor/patient [2] - 116:21, 132:10</p> <p>doctors [35] - 17:7, 17:8, 19:10, 20:11, 116:14, 116:15, 117:23, 118:1, 121:14, 121:22, 122:6, 123:18, 125:17, 127:17, 127:24, 128:23, 129:14, 129:25, 138:9, 156:23, 157:1, 157:25, 158:2, 167:23, 171:7, 185:13, 186:24, 193:20, 242:6, 242:8, 242:23, 247:10</p> <p>document [45] - 8:15, 9:3, 9:5, 9:10, 26:17, 35:9, 52:19, 52:21, 52:22, 66:23, 66:25, 68:12, 119:16, 119:22, 120:8, 124:16, 124:22, 125:1, 125:25, 126:2, 127:8, 138:11, 140:19, 143:21, 162:19, 162:21, 162:22, 163:15, 167:20, 173:16, 179:23, 179:24, 190:14, 191:1, 191:18, 192:12, 192:14, 197:11, 197:17, 198:4, 221:10, 263:23, 268:17, 270:5</p> <p>documentation [1] - 28:15</p>	<p>documented [1] - 165:22</p> <p>documents [21] - 7:12, 7:23, 8:6, 28:13, 29:22, 34:7, 34:8, 35:23, 41:22, 42:8, 42:21, 52:18, 102:11, 119:21, 138:15, 140:11, 140:17, 188:19, 254:19, 255:5, 270:9</p> <p>done [35] - 9:14, 23:1, 24:7, 40:10, 54:4, 71:20, 89:4, 113:12, 126:8, 129:4, 131:3, 141:13, 154:20, 204:24, 218:15, 218:18, 220:21, 223:3, 223:5, 223:17, 224:8, 226:25, 232:5, 232:9, 239:4, 240:5, 241:1, 244:19, 247:18, 250:10, 258:8, 258:9, 270:16, 270:21, 275:15</p> <p>door [1] - 21:3</p> <p>doors [1] - 21:13</p> <p>dosage [47] - 16:25, 47:4, 47:19, 47:20, 49:1, 49:20, 50:1, 55:23, 57:6, 57:17, 58:21, 93:22, 95:3, 95:7, 96:21, 96:23, 96:24, 96:25, 97:2, 97:3, 97:4, 97:5, 98:1, 98:4, 98:9, 98:10, 98:17, 100:5, 100:6, 100:12, 100:13, 100:15, 100:19, 100:23, 101:1, 101:5, 101:8, 101:10, 101:12, 101:13, 101:14, 101:16, 101:18, 101:19, 101:20</p> <p>dose [1] - 46:24</p> <p>dots [1] - 67:4</p> <p>dotted [2] - 193:25, 194:9</p> <p>Douglas [1] - 4:17</p> <p>down [36] - 17:2, 17:3, 20:8, 23:10, 24:20, 36:25, 40:10, 40:18, 43:9, 45:7, 45:10, 48:7, 52:17, 52:18, 60:21, 61:2, 67:3, 67:15, 71:7, 75:2, 76:16, 77:17, 87:20,</p>	<p>97:1, 98:7, 98:22, 120:17, 122:14, 142:7, 158:11, 193:23, 215:21, 233:11, 246:13, 259:6, 260:1</p> <p>downturn [1] - 11:4</p> <p>dozen [3] - 23:16, 150:20, 210:7</p> <p>dozens [1] - 150:14</p> <p>Dozens [1] - 150:16</p> <p>Dr [49] - 13:15, 13:16, 13:19, 18:17, 19:4, 19:6, 51:10, 51:20, 52:11, 52:19, 53:17, 53:18, 114:9, 114:10, 114:13, 114:16, 114:20, 115:5, 125:22, 126:6, 126:13, 128:16, 137:2, 150:13, 150:18, 151:25, 152:11, 154:6, 201:17, 202:3, 210:13, 210:16, 210:21, 212:1, 212:2, 212:13, 212:19, 212:21, 212:23, 213:8, 213:15, 220:20, 221:20, 222:1, 227:5, 230:12, 231:5, 244:23, 273:9</p> <p>dramatic [1] - 184:25</p> <p>draw [2] - 55:9, 250:12</p> <p>drawing [2] - 65:2, 130:23</p> <p>Drive [1] - 6:15</p> <p>driving [1] - 33:4</p> <p>dropping [4] - 45:10, 97:1, 98:7, 98:22</p> <p>drops [1] - 238:2</p> <p>DRUG [2] - 1:7, 1:13</p> <p>Drug [11] - 6:2, 20:2, 28:8, 45:16, 118:17, 118:21, 126:14, 163:10, 192:9, 274:9, 278:23</p> <p>drug [11] - 12:7, 70:21, 79:12, 145:22, 159:12, 193:5, 194:1, 194:2, 195:17, 257:4, 258:16</p> <p>drug's [1] - 141:3</p> <p>Drugs [2] - 138:13, 198:8</p> <p>drugs [28] - 17:11, 19:1, 19:21, 21:4,</p>
--	---	---	--	--

<p>61:20, 71:1, 71:5, 71:8, 75:14, 78:13, 80:19, 83:4, 84:1, 84:3, 84:5, 84:8, 93:25, 95:1, 142:11, 183:20, 194:6, 195:10, 196:5, 196:14, 198:12, 199:14, 200:1, 242:13</p> <p>DU45 [1] - 274:3</p> <p>DU45s [1] - 206:8</p> <p>due [46] - 23:18, 42:20, 76:9, 77:21, 77:24, 79:23, 81:6, 88:24, 89:3, 89:18, 89:21, 94:11, 97:8, 102:1, 102:3, 102:4, 106:4, 106:8, 109:16, 201:24, 204:24, 217:13, 217:17, 220:5, 220:6, 226:17, 227:4, 228:18, 229:10, 229:11, 233:10, 234:24, 235:1, 235:6, 236:8, 236:13, 237:22, 243:2, 244:19, 244:23, 245:24, 264:19, 267:23, 269:25, 270:14, 276:22</p> <p>duplication [1] - 266:13</p> <p>During [6] - 21:23, 129:25, 159:10, 169:20, 169:22, 171:18</p> <p>during [27] - 11:23, 22:24, 35:17, 42:16, 43:9, 46:21, 46:25, 47:5, 47:22, 50:3, 50:7, 50:12, 54:8, 54:12, 54:21, 55:8, 58:25, 59:5, 93:2, 127:19, 128:19, 130:7, 134:12, 161:20, 169:23, 222:18, 259:1</p> <p>duties [1] - 15:21</p> <p>duty [7] - 78:4, 78:10, 106:17, 160:2, 160:3, 199:24, 202:7</p>	<p>easier [2] - 60:14, 265:13</p> <p>easily [1] - 154:20</p> <p>East [3] - 3:5, 3:12, 4:18</p> <p>east [1] - 17:25</p> <p>easy [1] - 7:15</p> <p>Echo [1] - 100:18</p> <p>economic [1] - 11:4</p> <p>effect [3] - 13:22, 217:4, 261:15</p> <p>effective [18] - 23:20, 24:13, 28:25, 30:1, 30:11, 32:11, 76:5, 107:4, 107:9, 107:22, 108:4, 108:16, 109:2, 110:7, 146:7, 233:8, 251:19, 270:4</p> <p>effort [1] - 99:18</p> <p>Efforts [2] - 138:14, 163:11</p> <p>efforts [1] - 151:14</p> <p>eight [1] - 14:16</p> <p>Eighth [1] - 3:10</p> <p>either [11] - 26:12, 51:20, 73:5, 141:16, 182:1, 188:7, 213:24, 224:8, 239:18, 240:12, 260:9</p> <p>electronic [1] - 24:5</p> <p>eliminate [1] - 43:16</p> <p>ELIZABETH [1] - 6:14</p> <p>email [4] - 8:15, 8:16, 8:25, 9:12</p> <p>emails [3] - 9:3, 28:14, 42:22</p> <p>emergency [1] - 133:25</p> <p>emphasized [1] - 22:10</p> <p>employed [5] - 29:10, 82:2, 92:4, 123:22, 260:6</p> <p>employee [4] - 9:6, 123:25, 158:16, 260:8</p> <p>employees [15] - 9:12, 9:16, 11:17, 27:19, 27:22, 28:6, 36:14, 42:17, 54:8, 95:4, 148:4, 276:25, 277:3, 277:5, 277:13</p> <p>employer [1] - 118:18</p> <p>employment [9] - 9:7, 10:25, 15:6, 15:10, 15:23, 29:15, 158:7, 158:12</p> <p>Encino [1] - 3:18</p>	<p>encourage [1] - 141:24</p> <p>end [9] - 12:14, 21:22, 30:22, 87:24, 89:1, 133:20, 147:13, 218:7, 277:17</p> <p>ended [3] - 22:18, 22:19, 131:7</p> <p>endorsing [1] - 221:13</p> <p>enforcement [4] - 10:25, 16:5, 121:7, 185:1</p> <p>Enforcement [5] - 45:16, 118:18, 118:21, 163:10, 163:11</p> <p>engaged [1] - 166:24</p> <p>engaging [5] - 128:13, 129:12, 129:15, 145:19, 195:7</p> <p>enhancements [2] - 275:4, 275:9</p> <p>enormous [1] - 85:24</p> <p>ensure [1] - 132:8</p> <p>Ensure [1] - 192:10</p> <p>ensuring [1] - 148:18</p> <p>entails [1] - 21:2</p> <p>entered [1] - 22:1</p> <p>entire [4] - 12:16, 56:14, 112:17, 232:10</p> <p>entirely [2] - 77:6, 242:3</p> <p>entities [10] - 116:8, 133:15, 148:14, 155:22, 177:6, 185:11, 186:6, 186:8, 186:9, 272:19</p> <p>entitled [1] - 147:16</p> <p>entity [2] - 154:8, 156:6</p> <p>ENU [1] - 4:12</p> <p>epidemic [3] - 157:21, 178:15, 182:14</p> <p>era [1] - 60:10</p> <p>escalates [1] - 87:12</p> <p>escalating [1] - 243:6</p> <p>especially [2] - 9:3, 11:20</p> <p>essential [1] - 28:14</p> <p>Essentially [1] - 39:8</p> <p>essentially [5] - 16:4, 21:4, 29:20, 68:9, 93:15</p> <p>established [1] - 54:16</p> <p>estimate [5] - 216:24, 219:20, 236:10, 248:18, 249:18</p> <p>estimated [2] -</p>	<p>180:14, 180:20</p> <p>estimates [4] - 248:19, 249:2, 249:14, 250:14</p> <p>estimation [1] - 249:23</p> <p>et [4] - 1:7, 1:13, 278:22, 278:23</p> <p>etched [1] - 239:10</p> <p>Euson [2] - 264:18, 265:14</p> <p>evaluate [9] - 116:2, 116:4, 139:23, 149:10, 186:4, 186:7, 229:2, 239:11, 243:9</p> <p>evaluated [1] - 116:7</p> <p>evaluating [7] - 116:8, 133:19, 133:23, 134:20, 134:24, 272:20, 273:1</p> <p>evaluation [3] - 94:16, 236:25, 244:20</p> <p>evening [1] - 21:11</p> <p>event [1] - 233:25</p> <p>events [1] - 259:7</p> <p>eventually [1] - 16:25</p> <p>everywhere [1] - 275:22</p> <p>evidence [27] - 34:23, 51:2, 53:11, 59:2, 59:13, 66:11, 99:2, 99:3, 99:6, 99:9, 99:11, 102:14, 106:3, 106:7, 106:12, 106:23, 119:10, 126:19, 138:18, 162:20, 162:22, 174:7, 192:4, 197:19, 256:13, 267:6, 268:15</p> <p>exact [12] - 165:13, 196:15, 196:18, 220:18, 231:17, 232:25, 233:16, 235:4, 251:12, 251:17, 252:21, 253:13</p> <p>exactly [8] - 35:7, 80:6, 212:8, 220:19, 223:9, 235:18, 243:25, 273:12</p> <p>EXAMINATION [2] - 10:15, 115:12</p> <p>examination [9] - 30:20, 99:6, 119:21, 147:15, 154:23, 172:19, 217:2, 263:25</p>	<p>examinations [1] - 15:16</p> <p>examine [5] - 29:22, 63:12, 78:5, 109:23, 115:8</p> <p>examined [3] - 52:3, 141:2, 141:7</p> <p>example [17] - 65:12, 71:12, 90:6, 93:6, 95:3, 151:2, 176:10, 176:22, 181:17, 195:23, 204:17, 205:1, 230:24, 244:2, 245:9, 264:10</p> <p>examples [7] - 18:12, 20:1, 193:6, 193:25, 194:2, 194:6, 243:23</p> <p>exceed [3] - 12:1, 91:16, 251:1</p> <p>exceeded [7] - 12:1, 70:18, 72:4, 73:10, 73:15, 88:1, 88:17</p> <p>exceeding [1] - 246:6</p> <p>exceeds [2] - 89:2, 95:7</p> <p>except [3] - 174:1, 201:21, 226:16</p> <p>exception [8] - 119:25, 127:4, 165:1, 165:12, 169:13, 195:23, 202:6, 221:13</p> <p>exceptions [1] - 36:12</p> <p>excess [4] - 88:13, 89:23, 94:8, 97:22</p> <p>excessive [10] - 61:7, 61:23, 61:24, 63:20, 64:11, 70:5, 70:6, 70:16, 73:11, 73:14</p> <p>exclude [2] - 77:5, 271:25</p> <p>excluded [1] - 32:2</p> <p>excuse [2] - 7:17, 244:14</p> <p>Excuse [1] - 37:10</p> <p>executed [1] - 20:20</p> <p>Executive [1] - 12:15</p> <p>exemplar [2] - 66:7, 72:22</p> <p>exercise [5] - 43:21, 156:15, 236:16, 236:19, 267:23</p> <p>exercising [1] - 36:10</p> <p>exhibit [4] - 99:8, 174:17, 202:12, 244:6</p> <p>Exhibit [2] - 179:22, 236:8</p> <p>exhibits [1] - 261:4</p> <p>exist [3] - 106:17,</p>
--	--	--	---	--

E

early [4] - 22:16, 43:4, 113:13, 253:3

ease [1] - 231:5

<p>151:7, 251:8 existing [1] - 62:22 exists [1] - 152:2 expand [1] - 257:4 expanded [3] - 57:12, 141:23, 268:6 expect [4] - 94:15, 117:8, 240:3, 240:6 expectation [3] - 23:23, 94:14, 156:5 experience [16] - 20:22, 23:24, 24:1, 25:8, 61:12, 61:24, 80:15, 80:25, 83:11, 114:6, 114:23, 122:18, 149:24, 170:18, 185:19, 277:23 experienced [1] - 81:23 expert [40] - 10:4, 13:20, 25:19, 25:20, 30:9, 31:12, 31:16, 32:8, 33:7, 42:4, 43:17, 43:24, 46:14, 51:3, 51:4, 51:8, 51:13, 52:20, 53:14, 53:16, 53:19, 59:1, 114:5, 117:25, 119:20, 123:21, 123:22, 123:23, 123:25, 124:2, 146:21, 182:6, 188:3, 188:4, 196:23, 200:18, 214:22, 215:2, 254:19 experts [3] - 43:22, 115:4, 126:25 explain [15] - 10:21, 22:20, 27:10, 54:3, 55:10, 69:12, 85:10, 87:14, 87:19, 93:7, 94:22, 128:7, 160:25, 234:4, 241:16 explained [2] - 99:23, 201:23 explaining [2] - 166:5, 233:22 explains [1] - 226:19 explanation [1] - 90:25 export [1] - 180:15 express [1] - 203:24 expressed [2] - 142:10, 169:22 extensive [3] - 141:20, 141:22, 170:23 extent [3] - 32:10,</p>	<p>62:25, 63:1 extremely [1] - 120:17 eye [1] - 12:22</p> <p style="text-align: center;">F</p> <p>FABER [1] - 1:17 Faber [1] - 7:2 face [2] - 76:23, 228:1 facility [2] - 21:7, 25:1 fact [28] - 64:16, 65:8, 65:11, 65:12, 66:7, 76:17, 79:10, 116:25, 121:4, 136:19, 138:11, 149:3, 149:24, 155:10, 173:24, 174:18, 191:20, 196:19, 211:2, 217:19, 229:7, 236:4, 236:19, 256:9, 273:19, 273:22, 275:22, 276:24 factor [7] - 68:3, 110:25, 111:20, 125:13, 125:16, 143:14, 143:18 factors [5] - 125:11, 126:14, 139:18, 139:24, 143:10 facts [9] - 29:14, 35:17, 52:13, 53:15, 76:11, 188:6, 239:19, 260:25, 261:19 factual [9] - 28:21, 29:25, 142:2, 164:11, 164:23, 169:6, 170:15, 181:25, 183:8 factually [1] - 181:23 failed [5] - 24:23, 148:5, 151:2, 178:20, 237:11 fails [1] - 156:15 failure [5] - 24:13, 32:11, 107:9, 109:14, 228:15 failures [3] - 109:8, 110:24, 111:19 fair [4] - 115:20, 189:20, 199:22, 239:18 fairly [1] - 52:2 faith [1] - 264:1 fall [3] - 70:19, 71:7, 76:4 Fall [1] - 259:4 falls [1] - 93:10</p>	<p>falsifies [1] - 171:25 familiar [7] - 114:20, 117:3, 119:18, 173:18, 213:15, 263:20, 268:17 familiarize [1] - 258:16 family [4] - 78:13, 195:10, 196:5, 198:18 far [10] - 58:5, 58:6, 71:19, 91:2, 126:18, 131:2, 135:22, 213:20, 248:13, 261:6 FARRELL [173] - 2:3, 7:8, 10:3, 10:16, 13:4, 14:15, 14:23, 21:19, 25:5, 25:6, 25:21, 25:25, 26:4, 27:7, 27:9, 30:8, 32:10, 32:24, 32:25, 33:2, 33:6, 33:16, 33:18, 34:4, 34:13, 34:18, 34:24, 35:6, 35:13, 35:15, 36:5, 36:7, 36:20, 37:9, 40:17, 42:1, 42:6, 42:25, 43:6, 44:3, 44:5, 44:24, 45:2, 46:2, 46:17, 46:18, 47:13, 47:16, 50:21, 52:10, 53:22, 53:25, 59:19, 59:22, 59:23, 60:16, 60:19, 62:16, 62:18, 63:14, 63:17, 64:4, 64:9, 65:14, 66:3, 66:5, 66:18, 66:22, 68:18, 68:20, 69:1, 69:2, 69:18, 69:21, 70:8, 70:10, 72:17, 72:19, 72:21, 74:2, 74:9, 74:15, 74:25, 75:7, 75:24, 76:21, 77:7, 78:8, 79:8, 79:9, 80:11, 81:9, 81:13, 81:16, 81:19, 82:8, 82:14, 85:23, 86:5, 86:23, 86:24, 87:6, 87:10, 90:13, 90:22, 90:24, 91:3, 91:4, 91:22, 92:1, 92:2, 94:4, 96:8, 96:9, 99:13, 99:15, 99:16, 99:21, 100:17, 102:25, 103:2, 106:22, 107:14, 107:20, 108:10, 108:22, 109:25, 110:4,</p>	<p>110:14, 110:17, 110:23, 111:16, 112:21, 113:7, 113:11, 113:17, 113:24, 114:1, 115:7, 119:13, 119:15, 125:23, 126:21, 138:21, 145:4, 145:7, 146:22, 154:10, 165:6, 166:2, 172:15, 172:17, 174:10, 174:20, 187:12, 187:16, 192:6, 197:21, 197:25, 202:20, 202:24, 207:11, 207:17, 209:4, 221:8, 233:21, 234:3, 234:11, 234:14, 239:6, 263:15, 263:19, 263:21 Farrell [44] - 2:4, 2:15, 7:9, 14:3, 14:14, 25:24, 30:24, 32:23, 35:12, 36:17, 40:13, 44:4, 46:1, 46:16, 52:9, 63:13, 65:18, 65:25, 68:16, 68:25, 69:14, 74:8, 78:23, 79:7, 80:10, 81:15, 81:21, 85:22, 86:22, 87:5, 90:12, 90:23, 99:11, 106:20, 107:19, 113:23, 131:4, 187:25, 202:19, 218:24, 243:18, 244:15, 263:18 Farrell's [1] - 115:19 fault [1] - 277:11 faulted [1] - 181:3 faults [1] - 177:21 FCRR [1] - 6:18 FDA [3] - 138:5, 141:2 features [1] - 74:22 February [4] - 125:6, 164:16, 164:19, 231:5 Federal [9] - 37:6, 39:11, 40:20, 120:21, 248:22, 249:4, 250:15, 266:6, 269:24 federal [4] - 121:6, 257:12, 269:22, 270:7 feed [1] - 192:16 feeding [1] - 19:16</p>	<p>feet [1] - 85:1 fellow [2] - 260:10, 260:12 felt [1] - 178:5 few [8] - 25:25, 113:24, 114:2, 167:21, 224:25, 240:1, 265:20, 273:3 fictional [2] - 87:11, 87:15 field [11] - 30:9, 115:4, 164:5, 164:13, 164:25, 165:8, 166:14, 166:21, 167:8, 167:11, 169:22 fields [1] - 33:7 fifth [2] - 136:11, 160:2 fight [1] - 178:8 fighths [1] - 18:22 figure [2] - 220:9, 273:18 Figure [2] - 192:14, 193:5 file [4] - 23:23, 23:24, 24:4, 259:11 filed [2] - 30:17, 264:10 files [27] - 23:12, 23:17, 23:18, 23:19, 24:2, 24:5, 24:8, 24:12, 26:6, 26:18, 28:9, 28:11, 42:19, 42:20, 102:5, 102:10, 103:6, 228:4, 228:9, 228:10, 228:11, 244:23, 269:22, 269:25, 270:13, 270:14 fill [7] - 95:14, 129:10, 130:18, 148:22, 160:7, 216:16, 231:15 filled [4] - 129:14, 130:20, 218:12, 231:16 filling [6] - 95:5, 129:20, 130:1, 130:2, 131:8, 132:11 final [5] - 14:22, 29:6, 43:2, 94:20, 95:10 finally [4] - 28:17, 97:4, 101:3, 101:7 findings [25] - 14:22, 24:9, 26:9, 26:12, 28:21, 29:15, 29:25, 30:13, 43:2, 44:7, 44:18, 47:8, 47:18,</p>
---	--	--	---	---

<p>50:16, 50:19, 51:21, 55:11, 96:2, 96:10, 96:17, 97:25, 98:15, 100:1, 100:20, 101:9</p> <p>finish [3] - 229:20, 262:15, 262:16</p> <p>finished [1] - 167:6</p> <p>finishes [1] - 77:24</p> <p>fire [5] - 89:5, 89:8, 97:14, 102:2</p> <p>Firm [2] - 3:4, 3:7</p> <p>First [1] - 141:20</p> <p>first [77] - 10:24, 13:13, 13:20, 15:5, 15:18, 20:2, 21:5, 23:10, 27:13, 28:6, 37:19, 42:24, 44:8, 47:24, 53:14, 58:3, 58:8, 58:15, 65:4, 71:4, 85:3, 85:8, 96:14, 97:10, 97:23, 104:22, 110:2, 111:24, 146:23, 146:25, 169:20, 175:11, 175:18, 180:5, 181:9, 194:16, 196:3, 210:17, 214:7, 217:13, 217:19, 222:11, 226:5, 226:24, 227:1, 227:7, 227:10, 229:12, 231:1, 231:10, 231:18, 231:20, 232:10, 232:25, 233:3, 233:5, 234:23, 237:23, 245:22, 246:6, 246:10, 246:22, 246:24, 247:7, 247:14, 254:5, 254:8, 256:19, 257:2, 266:13, 268:4, 268:11, 268:15, 269:3, 269:7</p> <p>fit [3] - 115:24, 215:19, 225:19</p> <p>five [9] - 11:3, 12:6, 71:5, 105:24, 113:12, 159:3, 205:23, 222:15, 277:21</p> <p>fix [1] - 110:18</p> <p>fixed [7] - 85:8, 89:15, 97:24, 226:24, 243:2, 243:7, 243:13</p> <p>fixing [1] - 247:14</p> <p>FL [1] - 2:14</p> <p>flag [14] - 84:15,</p>	<p>222:21, 228:25, 231:25, 232:22, 233:2, 233:5, 234:6, 234:21, 244:18, 247:24, 248:6, 248:11, 275:7</p> <p>flagged [31] - 39:16, 78:10, 79:1, 91:18, 96:14, 96:21, 96:24, 98:3, 98:5, 98:18, 100:2, 100:4, 102:16, 214:13, 215:9, 216:9, 216:11, 216:19, 218:18, 227:7, 227:11, 227:14, 227:22, 228:5, 228:13, 228:23, 230:9, 230:10, 232:17, 247:20</p> <p>flagging [10] - 53:2, 84:16, 199:19, 199:20, 208:13, 214:6, 238:2, 241:7, 245:5, 250:14</p> <p>flags [8] - 96:2, 132:12, 214:7, 231:11, 231:13, 275:10, 275:12, 275:14</p> <p>Flaherty [1] - 5:14</p> <p>FLAHIVE [1] - 5:10</p> <p>flaw [1] - 109:17</p> <p>flexibility [1] - 84:9</p> <p>flip [3] - 9:10, 42:24, 176:18</p> <p>Floor [1] - 3:5</p> <p>Florida [4] - 20:5, 20:8, 20:11, 24:20</p> <p>flow [8] - 17:2, 17:3, 29:12, 45:20, 75:14, 76:16, 92:6, 194:6</p> <p>flows [2] - 75:18, 77:17</p> <p>focus [7] - 139:18, 180:13, 194:9, 206:1, 219:7, 225:13, 254:23</p> <p>focused [2] - 16:14, 142:11</p> <p>focusing [1] - 147:10</p> <p>FOIA [1] - 38:3</p> <p>follow [7] - 24:17, 76:1, 88:4, 114:2, 134:1, 172:11, 215:4</p> <p>follow-up [3] - 114:2, 134:1, 215:4</p> <p>followed [5] - 14:21, 217:6, 218:5, 218:9, 218:13</p>	<p>following [9] - 27:20, 199:13, 227:3, 233:3, 237:4, 237:13, 238:25, 240:14, 275:24</p> <p>follows [6] - 7:5, 113:20, 127:23, 129:8, 164:22, 232:25</p> <p>FOR [1] - 1:1</p> <p>Force [4] - 12:5, 12:6, 15:8, 18:3</p> <p>force [1] - 141:23</p> <p>forced [1] - 178:13</p> <p>foregoing [1] - 278:20</p> <p>foregone [1] - 51:24</p> <p>foreshadow [1] - 77:9</p> <p>forfeiture [1] - 265:1</p> <p>forget [1] - 55:20</p> <p>forgot [1] - 17:9</p> <p>form [4] - 191:14, 194:17, 256:21, 275:2</p> <p>formally [1] - 15:9</p> <p>format [1] - 39:25</p> <p>former [5] - 118:18, 121:20, 123:6, 123:25, 223:1</p> <p>formerly [1] - 122:5</p> <p>forming [1] - 138:15</p> <p>forth [1] - 136:9</p> <p>forward [6] - 20:23, 23:8, 81:14, 158:10, 240:9, 240:12</p> <p>foundation [7] - 13:14, 30:3, 51:5, 119:17, 119:22, 126:21, 174:13</p> <p>four [20] - 19:12, 19:16, 19:17, 68:3, 68:7, 68:9, 69:6, 69:9, 70:1, 70:11, 71:14, 73:10, 194:1, 196:13, 198:11, 199:13, 231:17, 240:11, 274:19</p> <p>fourth [2] - 257:1, 274:17</p> <p>frame [22] - 24:3, 46:6, 46:21, 47:1, 47:6, 49:2, 49:14, 49:22, 50:3, 50:12, 54:12, 58:7, 62:12, 62:14, 67:12, 104:16, 129:25, 134:2, 251:3, 252:20, 252:21, 252:25</p> <p>frames [4] - 47:22, 50:7, 54:21, 59:5</p> <p>framework [1] - 26:23</p>	<p>Frank [1] - 263:21</p> <p>frankly [1] - 210:8</p> <p>fraudulently [1] - 172:1</p> <p>fraught [1] - 219:1</p> <p>free [3] - 95:16, 195:10, 196:5</p> <p>frequency [6] - 83:1, 203:7, 204:9, 204:14, 204:20, 205:9</p> <p>friends [3] - 195:10, 196:5, 198:18</p> <p>front [6] - 13:10, 122:5, 157:5, 179:20, 197:11, 199:9</p> <p>Fruth [3] - 55:5, 55:14, 57:1</p> <p>Frye [1] - 157:7</p> <p>fulfilled [1] - 135:4</p> <p>full [6] - 81:14, 140:9, 143:21, 169:20, 185:15, 196:17</p> <p>FULLER [6] - 2:15, 7:11, 7:14, 7:21, 7:25, 8:3</p> <p>Fuller [4] - 2:4, 2:15, 7:10, 7:19</p> <p>fully [6] - 26:17, 124:6, 159:24, 185:1, 240:6, 276:15</p> <p>function [3] - 15:3, 84:13, 93:12</p> <p>functioning [2] - 24:15, 29:4</p> <p>fundamental [1] - 147:9</p> <p>funding [1] - 12:2</p> <p>future [5] - 77:12, 78:11, 79:11, 89:16, 104:11</p>	<p>General [4] - 38:8, 135:22, 138:12, 179:20</p> <p>general [13] - 16:10, 26:22, 42:7, 45:3, 54:1, 64:10, 80:9, 84:24, 98:14, 117:10, 160:19, 199:21, 236:12</p> <p>Generally [3] - 119:7, 133:25, 134:10</p> <p>generally [15] - 17:10, 41:17, 80:18, 83:12, 83:20, 92:11, 122:11, 156:18, 160:8, 177:20, 187:5, 226:16, 230:19, 242:1, 244:7</p> <p>generate [3] - 52:2, 215:9, 247:20</p> <p>gentleman [1] - 18:16</p> <p>geographic [6] - 17:20, 56:3, 59:8, 59:11, 126:22, 207:11</p> <p>geography [1] - 17:22</p> <p>George [1] - 264:18</p> <p>Gitchell [1] - 37:22</p> <p>given [13] - 8:7, 136:15, 137:14, 155:11, 158:6, 159:13, 176:10, 176:13, 181:4, 254:19, 262:7, 262:9, 262:11</p> <p>glass [1] - 270:20</p> <p>golden [1] - 82:15</p> <p>governed [1] - 117:5</p> <p>Government [1] - 254:24</p> <p>government [8] - 127:5, 156:6, 170:16, 190:15, 191:22, 191:23, 236:5, 257:3</p> <p>governs [1] - 117:6</p> <p>graduated [1] - 15:16</p> <p>grams [11] - 67:19, 68:8, 69:8, 69:12, 69:23, 69:25, 70:11, 71:25, 72:4, 72:5</p> <p>grant [1] - 178:14</p> <p>graph [5] - 56:12, 56:21, 58:20, 94:8, 244:6</p> <p>graphically [1] - 183:6</p> <p>gray [2] - 58:22, 161:1</p> <p>great [1] - 124:4</p> <p>green [2] - 45:15, 193:24</p>
G				
<p>GA [1] - 137:6</p> <p>gain [1] - 27:17</p> <p>game [1] - 79:1</p> <p>GAO [5] - 139:11, 139:14, 139:24, 140:8, 140:16</p> <p>gap [3] - 201:21, 274:11, 274:13</p> <p>gathered [1] - 23:8</p> <p>gathering [1] - 249:22</p> <p>gears [3] - 190:13, 250:23, 269:21</p> <p>Geldhof [2] - 32:2, 108:8</p> <p>gels [1] - 17:1</p>				

<p>GRETCHEN [1] - 6:7 grew [1] - 19:2 ground [1] - 31:13 grounds [1] - 31:10 Group [2] - 20:3, 28:8 group [4] - 18:3, 21:8, 41:8, 272:18 groups [6] - 19:12, 19:16, 19:17, 92:22, 116:13, 186:22 grow [1] - 245:7 growth [1] - 245:4 guess [17] - 18:20, 99:13, 117:8, 117:15, 117:16, 122:11, 123:8, 123:15, 123:23, 124:18, 135:12, 189:12, 223:5, 228:15, 259:25, 260:6, 274:13 guidance [25] - 14:20, 33:21, 33:23, 34:5, 34:16, 35:4, 35:5, 36:18, 36:24, 37:1, 37:8, 37:12, 37:23, 38:1, 38:12, 41:8, 41:18, 82:18, 118:7, 118:8, 178:21, 265:25, 266:19, 268:17, 268:21 guide [2] - 118:5, 270:11 Guidelines [1] - 41:3 guidelines [2] - 41:8, 160:19 guilty [1] - 19:6 gun [1] - 16:6 Gupta [3] - 125:22, 126:6, 126:13 Gustin [1] - 58:19</p>	<p>124:22 handle [7] - 16:7, 16:16, 17:4, 17:10, 21:13, 38:13, 155:20 Handlers [2] - 38:15, 38:18 handling [5] - 21:4, 22:24, 28:15, 95:5, 181:7 hands [1] - 76:4 hang [1] - 94:25 happy [1] - 14:8 HARDIN [1] - 5:3 harm [5] - 25:1, 162:9, 162:10, 218:19, 218:21 Harvard [8] - 20:2, 20:10, 20:21, 21:15, 21:18, 22:3, 22:5, 28:8 Hawkins [1] - 3:7 HD [2] - 264:10, 264:18 HDMA [2] - 41:3, 41:4 head [6] - 11:24, 38:25, 121:10, 121:20, 123:6, 134:14 heading [7] - 120:15, 168:1, 168:3, 184:21, 184:23, 197:14, 198:7 headquarters [2] - 26:10, 167:2 Health [38] - 4:11, 5:2, 38:3, 40:23, 45:13, 46:6, 47:21, 49:6, 49:11, 55:17, 57:10, 57:21, 57:24, 59:24, 64:17, 66:7, 66:11, 67:8, 68:4, 68:11, 69:3, 70:15, 70:23, 71:19, 71:24, 72:25, 97:1, 98:7, 98:20, 100:6, 100:25, 101:14, 102:12, 104:14, 105:15, 108:3, 109:1, 271:5 Health's [3] - 46:5, 67:22, 86:6 healthcare [4] - 133:18, 133:23, 134:9, 195:17 hear [16] - 30:23, 31:7, 31:23, 32:20, 33:11, 33:14, 43:15, 51:22, 62:25, 65:16, 74:3, 137:5, 256:2, 263:6, 263:10, 277:2 heard [9] - 31:14,</p>	<p>31:18, 64:10, 78:2, 125:22, 133:8, 133:12, 133:15, 273:18 hearing [8] - 16:2, 18:20, 37:5, 39:10, 113:14, 121:24, 157:7, 265:6 Hearsay [1] - 172:17 hearsay [9] - 9:5, 119:15, 119:25, 126:21, 127:4, 172:17, 263:19, 263:22 heart [1] - 32:2 heated [1] - 261:10 held [5] - 76:7, 76:25, 77:14, 78:13, 81:6 help [2] - 211:10, 212:19 helped [6] - 137:15, 137:19, 144:12, 177:24, 178:15, 178:17 helpful [7] - 13:7, 20:23, 27:4, 34:1, 34:25, 36:2, 222:22 Henry [3] - 154:2, 154:4, 155:6 heroin [1] - 12:7 HESTER [1] - 5:9 high [7] - 82:19, 150:16, 151:3, 181:20, 209:22, 209:24, 210:9 higher [2] - 18:11, 187:2 highest [11] - 88:1, 88:7, 88:17, 89:19, 231:10, 246:24, 247:2, 247:3, 247:9, 276:6 highlight [4] - 139:16, 163:25, 232:3, 265:13 highlighted [2] - 142:8, 265:17 highly [1] - 170:22 Hilliard [1] - 58:18 himself [3] - 52:2, 52:3, 123:8 HIPAA [1] - 149:7 hired [5] - 15:9, 159:16, 223:22, 254:18, 277:5 hiring [2] - 277:3, 277:13 historically [1] - 36:25 histories [1] - 170:19 history [8] - 22:21,</p>	<p>25:4, 25:8, 25:16, 37:1, 154:17, 154:19, 170:10 hit [1] - 93:19 hits [1] - 75:21 hold [8] - 16:15, 75:7, 77:20, 88:16, 92:18, 94:14, 113:4, 261:16 Holder [1] - 40:24 holding [1] - 66:6 holds [2] - 75:22, 75:25 honest [1] - 20:23 Honor [428] - 7:8, 7:22, 8:3, 8:4, 8:21, 8:24, 9:9, 9:22, 10:13, 10:23, 13:11, 14:1, 14:5, 15:11, 16:3, 16:14, 18:15, 20:2, 20:15, 21:2, 21:21, 22:23, 25:3, 25:13, 26:25, 27:13, 29:20, 30:16, 31:15, 31:21, 32:2, 32:24, 34:3, 34:6, 34:17, 35:6, 35:8, 35:13, 36:1, 38:20, 39:15, 39:16, 40:2, 40:7, 40:10, 40:14, 41:20, 42:10, 43:10, 44:14, 44:17, 45:6, 45:19, 46:13, 46:17, 47:2, 47:9, 47:23, 49:7, 49:22, 50:14, 50:17, 50:24, 51:17, 52:6, 52:10, 53:10, 53:22, 54:18, 54:22, 55:2, 55:4, 56:5, 56:10, 56:15, 56:25, 57:6, 57:14, 57:20, 58:10, 58:15, 59:6, 59:16, 60:11, 60:14, 60:19, 60:23, 61:13, 62:2, 62:23, 63:16, 64:13, 64:15, 65:17, 66:3, 66:17, 67:2, 68:3, 69:11, 69:20, 70:8, 71:2, 71:18, 72:5, 73:12, 73:18, 73:23, 74:10, 74:20, 75:5, 75:6, 76:2, 76:22, 77:14, 77:25, 78:18, 78:19, 78:22, 79:17, 79:20, 79:25, 80:20, 80:24, 81:8, 82:4, 82:17, 82:21, 83:10, 83:24, 84:17, 85:3, 85:18, 86:3, 86:13, 86:14, 86:17, 87:13, 87:20, 88:19, 88:25,</p>	<p>89:12, 89:25, 90:6, 91:3, 91:19, 92:5, 92:17, 93:9, 93:16, 93:18, 94:15, 96:4, 96:12, 96:20, 97:18, 98:3, 98:16, 98:22, 99:3, 99:20, 100:10, 100:16, 100:22, 102:9, 102:13, 102:17, 103:8, 103:18, 103:21, 104:3, 104:13, 105:11, 105:16, 105:21, 106:1, 106:6, 106:11, 106:16, 106:21, 107:2, 107:7, 107:11, 108:2, 108:7, 108:9, 108:19, 108:21, 109:5, 109:10, 109:20, 110:10, 110:20, 111:3, 111:23, 112:8, 112:20, 113:1, 113:6, 113:17, 113:24, 114:12, 114:15, 114:17, 114:19, 114:24, 115:6, 115:9, 115:10, 115:21, 116:3, 116:6, 116:11, 116:19, 116:24, 117:7, 117:10, 117:16, 117:25, 118:6, 118:10, 118:16, 118:19, 119:13, 121:3, 121:9, 121:17, 121:25, 122:8, 122:25, 124:10, 124:19, 124:20, 124:25, 125:12, 126:7, 126:17, 126:20, 127:13, 127:21, 128:6, 128:9, 129:1, 131:10, 131:23, 133:3, 134:1, 134:3, 134:24, 135:7, 135:13, 137:21, 138:10, 138:19, 141:11, 142:17, 144:10, 144:14, 145:4, 145:13, 146:16, 147:19, 148:8, 148:24, 149:13, 150:25, 151:6, 151:16, 152:8, 154:10, 154:19, 155:1,</p>
H				
<p>hairs [2] - 123:24, 252:4 half [3] - 11:23, 75:1, 150:20 hall [1] - 115:15 hand [17] - 10:8, 11:17, 66:6, 66:19, 67:16, 71:19, 120:9, 133:22, 134:2, 139:7, 139:12, 139:13, 140:7, 152:15, 162:7, 179:25, 192:13 hand-picked [1] - 11:17 handed [2] - 118:13,</p>	<p>124:22 handle [7] - 16:7, 16:16, 17:4, 17:10, 21:13, 38:13, 155:20 Handlers [2] - 38:15, 38:18 handling [5] - 21:4, 22:24, 28:15, 95:5, 181:7 hands [1] - 76:4 hang [1] - 94:25 happy [1] - 14:8 HARDIN [1] - 5:3 harm [5] - 25:1, 162:9, 162:10, 218:19, 218:21 Harvard [8] - 20:2, 20:10, 20:21, 21:15, 21:18, 22:3, 22:5, 28:8 Hawkins [1] - 3:7 HD [2] - 264:10, 264:18 HDMA [2] - 41:3, 41:4 head [6] - 11:24, 38:25, 121:10, 121:20, 123:6, 134:14 heading [7] - 120:15, 168:1, 168:3, 184:21, 184:23, 197:14, 198:7 headquarters [2] - 26:10, 167:2 Health [38] - 4:11, 5:2, 38:3, 40:23, 45:13, 46:6, 47:21, 49:6, 49:11, 55:17, 57:10, 57:21, 57:24, 59:24, 64:17, 66:7, 66:11, 67:8, 68:4, 68:11, 69:3, 70:15, 70:23, 71:19, 71:24, 72:25, 97:1, 98:7, 98:20, 100:6, 100:25, 101:14, 102:12, 104:14, 105:15, 108:3, 109:1, 271:5 Health's [3] - 46:5, 67:22, 86:6 healthcare [4] - 133:18, 133:23, 134:9, 195:17 hear [16] - 30:23, 31:7, 31:23, 32:20, 33:11, 33:14, 43:15, 51:22, 62:25, 65:16, 74:3, 137:5, 256:2, 263:6, 263:10, 277:2 heard [9] - 31:14,</p>	<p>31:18, 64:10, 78:2, 125:22, 133:8, 133:12, 133:15, 273:18 hearing [8] - 16:2, 18:20, 37:5, 39:10, 113:14, 121:24, 157:7, 265:6 Hearsay [1] - 172:17 hearsay [9] - 9:5, 119:15, 119:25, 126:21, 127:4, 172:17, 263:19, 263:22 heart [1] - 32:2 heated [1] - 261:10 held [5] - 76:7, 76:25, 77:14, 78:13, 81:6 help [2] - 211:10, 212:19 helped [6] - 137:15, 137:19, 144:12, 177:24, 178:15, 178:17 helpful [7] - 13:7, 20:23, 27:4, 34:1, 34:25, 36:2, 222:22 Henry [3] - 154:2, 154:4, 155:6 heroin [1] - 12:7 HESTER [1] - 5:9 high [7] - 82:19, 150:16, 151:3, 181:20, 209:22, 209:24, 210:9 higher [2] - 18:11, 187:2 highest [11] - 88:1, 88:7, 88:17, 89:19, 231:10, 246:24, 247:2, 247:3, 247:9, 276:6 highlight [4] - 139:16, 163:25, 232:3, 265:13 highlighted [2] - 142:8, 265:17 highly [1] - 170:22 Hilliard [1] - 58:18 himself [3] - 52:2, 52:3, 123:8 HIPAA [1] - 149:7 hired [5] - 15:9, 159:16, 223:22, 254:18, 277:5 hiring [2] - 277:3, 277:13 historically [1] - 36:25 histories [1] - 170:19 history [8] - 22:21,</p>	<p>25:4, 25:8, 25:16, 37:1, 154:17, 154:19, 170:10 hit [1] - 93:19 hits [1] - 75:21 hold [8] - 16:15, 75:7, 77:20, 88:16, 92:18, 94:14, 113:4, 261:16 Holder [1] - 40:24 holding [1] - 66:6 holds [2] - 75:22, 75:25 honest [1] - 20:23 Honor [428] - 7:8, 7:22, 8:3, 8:4, 8:21, 8:24, 9:9, 9:22, 10:13, 10:23, 13:11, 14:1, 14:5, 15:11, 16:3, 16:14, 18:15, 20:2, 20:15, 21:2, 21:21, 22:23, 25:3, 25:13, 26:25, 27:13, 29:20, 30:16, 31:15, 31:21, 32:2, 32:24, 34:3, 34:6, 34:17, 35:6, 35:8, 35:13, 36:1, 38:20, 39:15, 39:16, 40:2, 40:7, 40:10, 40:14, 41:20, 42:10, 43:10, 44:14, 44:17, 45:6, 45:19, 46:13, 46:17, 47:2, 47:9, 47:23, 49:7, 49:22, 50:14, 50:17, 50:24, 51:17, 52:6, 52:10, 53:10, 53:22, 54:18, 54:22, 55:2, 55:4, 56:5, 56:10, 56:15, 56:25, 57:6, 57:14, 57:20, 58:10, 58:15, 59:6, 59:16, 60:11, 60:14, 60:19, 60:23, 61:13, 62:2, 62:23, 63:16, 64:13, 64:15, 65:17, 66:3, 66:17, 67:2, 68:3, 69:11, 69:20, 70:8, 71:2, 71:18, 72:5, 73:12, 73:18, 73:23, 74:10, 74:20, 75:5, 75:6, 76:2, 76:22, 77:14, 77:25, 78:18, 78:19, 78:22, 79:17, 79:20, 79:25, 80:20, 80:24, 81:8, 82:4, 82:17, 82:21, 83:10, 83:24, 84:17, 85:3, 85:18, 86:3, 86:13, 86:14, 86:17, 87:13, 87:20, 88:19, 88:25,</p>	<p>89:12, 89:25, 90:6, 91:3, 91:19, 92:5, 92:17, 93:9, 93:16, 93:18, 94:15, 96:4, 96:12, 96:20, 97:18, 98:3, 98:16, 98:22, 99:3, 99:20, 100:10, 100:16, 100:22, 102:9, 102:13, 102:17, 103:8, 103:18, 103:21, 104:3, 104:13, 105:11, 105:16, 105:21, 106:1, 106:6, 106:11, 106:16, 106:21, 107:2, 107:7, 107:11, 108:2, 108:7, 108:9, 108:19, 108:21, 109:5, 109:10, 109:20, 110:10, 110:20, 111:3, 111:23, 112:8, 112:20, 113:1, 113:6, 113:17, 113:24, 114:12, 114:15, 114:17, 114:19, 114:24, 115:6, 115:9, 115:10, 115:21, 116:3, 116:6, 116:11, 116:19, 116:24, 117:7, 117:10, 117:16, 117:25, 118:6, 118:10, 118:16, 118:19, 119:13, 121:3, 121:9, 121:17, 121:25, 122:8, 122:25, 124:10, 124:19, 124:20, 124:25, 125:12, 126:7, 126:17, 126:20, 127:13, 127:21, 128:6, 128:9, 129:1, 131:10, 131:23, 133:3, 134:1, 134:3, 134:24, 135:7, 135:13, 137:21, 138:10, 138:19, 141:11, 142:17, 144:10, 144:14, 145:4, 145:13, 146:16, 147:19, 148:8, 148:24, 149:13, 150:25, 151:6, 151:16, 152:8, 154:10, 154:19, 155:1,</p>

155:8, 155:14, 155:21, 156:14, 156:25, 158:21, 159:21, 160:17, 160:24, 161:2, 161:19, 162:8, 162:18, 165:6, 165:23, 166:25, 170:17, 172:15, 174:8, 174:10, 174:20, 176:15, 177:14, 178:3, 179:8, 179:14, 179:17, 180:18, 180:22, 181:1, 182:1, 187:12, 187:19, 188:8, 188:12, 190:11, 190:17, 190:21, 191:5, 191:16, 192:3, 192:6, 193:2, 193:22, 195:1, 195:5, 195:22, 197:16, 197:19, 197:23, 198:23, 199:1, 200:5, 200:10, 200:12, 202:6, 203:12, 204:1, 204:16, 205:22, 205:25, 206:15, 206:19, 207:1, 207:11, 207:17, 208:5, 208:9, 208:12, 209:4, 209:5, 209:11, 209:13, 209:15, 209:19, 210:23, 213:2, 213:7, 214:2, 216:12, 216:18, 216:22, 217:11, 217:21, 218:2, 218:10, 218:14, 218:20, 220:17, 220:24, 221:11, 221:22, 222:8, 222:10, 223:17, 224:9, 224:24, 225:4, 226:11, 227:24, 228:3, 228:17, 231:14, 233:6, 233:17, 234:16, 234:23, 235:24, 236:10, 236:15, 236:18, 239:6, 239:10, 240:10, 241:12, 241:22, 243:1, 244:11, 245:8, 245:16, 247:17, 250:17, 251:8,	251:12, 255:15, 255:20, 256:4, 256:11, 256:12, 258:18, 259:16, 262:15, 263:15, 263:19, 265:2, 266:21, 267:2, 267:5, 267:15, 268:19, 268:24, 269:5, 269:20, 270:6, 270:17, 271:3, 271:7, 271:20, 272:23, 273:15, 277:18, 277:22, 277:25, 278:4, 278:12 HONORABLE [1] - 1:17 Honorable [1] - 7:1 hope [6] - 55:9, 59:17, 118:1, 123:15, 184:16 hopefully [3] - 27:24, 43:13, 60:14 hoping [1] - 43:6 horizontal [2] - 55:24, 57:7 horrible [1] - 235:14 Hospital [1] - 272:3 hospital [2] - 84:2, 272:5 hospitals [5] - 271:18, 271:19, 272:2, 272:9, 273:8 house [1] - 15:12 huge [2] - 39:8, 83:24 hundred [12] - 48:19, 80:18, 85:1, 210:1, 210:2, 210:4, 231:21, 231:22, 231:24, 232:18, 233:14, 234:21 hundreds [4] - 150:10, 186:22, 186:23, 207:9 HUNTINGTON [1] - 1:4 Huntington [76] - 3:10, 4:1, 42:12, 44:12, 46:20, 46:25, 47:5, 50:2, 54:25, 56:4, 56:14, 57:18, 59:4, 59:9, 67:6, 70:20, 97:17, 103:5, 106:5, 106:10, 106:14, 106:25, 107:6, 107:24, 108:6, 108:17, 109:3, 111:1, 111:21, 112:6,	112:25, 127:16, 127:18, 128:13, 128:23, 129:6, 129:11, 129:20, 134:13, 134:21, 135:9, 135:23, 136:1, 144:17, 149:16, 150:14, 150:23, 151:19, 152:20, 153:2, 154:5, 172:24, 179:5, 179:12, 185:16, 186:3, 194:23, 206:14, 206:17, 206:22, 207:22, 208:21, 208:22, 242:7, 244:1, 244:3, 244:8, 271:1, 271:4, 271:13, 272:1, 272:20, 273:1, 273:17, 278:22 Huntington-Cabell [23] - 46:20, 46:25, 47:5, 50:2, 54:25, 59:4, 97:17, 103:5, 106:5, 106:10, 106:14, 106:25, 107:6, 107:24, 108:6, 108:17, 109:3, 111:1, 111:21, 112:6, 112:25, 207:22, 273:17 Huntington/Cabell [15] - 127:25, 136:24, 137:7, 137:16, 137:20, 162:14, 167:8, 171:8, 171:11, 171:14, 172:6, 173:5, 185:21, 185:24, 194:21 hydrocodone [37] - 39:8, 46:23, 47:19, 48:23, 48:24, 49:9, 49:20, 49:24, 50:1, 54:24, 56:10, 56:22, 58:22, 59:3, 61:20, 96:18, 96:24, 97:6, 98:1, 98:5, 98:11, 98:18, 98:21, 98:23, 100:4, 100:8, 100:15, 100:24, 101:2, 101:5, 101:12, 101:16, 101:20, 106:9, 106:14, 250:6, 272:24	I idea [5] - 37:1, 205:12, 237:3, 243:21, 248:14 identification [1] - 39:20 identified [22] - 24:17, 34:20, 59:1, 63:19, 63:20, 81:22, 84:20, 85:20, 85:21, 86:4, 102:7, 124:11, 128:12, 145:19, 206:3, 206:12, 226:23, 239:17, 251:15, 257:23, 264:13, 275:24 identifies [4] - 82:1, 88:7, 235:22, 235:25 identify [27] - 24:23, 30:5, 44:15, 46:19, 46:23, 47:3, 49:25, 50:6, 50:11, 54:20, 55:1, 56:3, 82:24, 84:17, 84:24, 109:2, 128:11, 129:8, 132:11, 140:9, 210:6, 210:11, 223:3, 236:17, 236:20, 246:3, 251:10 identifying [3] - 73:15, 242:2, 251:20 ignores [1] - 242:3 II [3] - 106:24, 119:8, 180:10 III [1] - 61:19 IIIs [1] - 61:19 illegal [1] - 185:24 illegitimately [1] - 127:25 illicit [20] - 12:7, 17:17, 22:25, 30:12, 38:14, 38:21, 76:4, 104:6, 104:8, 107:5, 107:23, 108:5, 108:17, 110:8, 111:1, 111:21, 112:5, 112:24, 130:7, 260:18 illustrate [3] - 35:4, 230:6, 232:15 illustrated [2] - 93:20, 183:6 illustrates [1] - 74:21 illustration [11] - 60:23, 90:1, 92:11, 93:18, 215:8, 230:13, 230:14, 230:17, 230:22,	231:1, 231:3 illustrations [7] - 219:10, 220:22, 222:2, 222:5, 223:13, 223:18, 224:12 ILR [1] - 66:13 image [2] - 192:19, 192:20 Immediate [2] - 20:25, 21:14 immediate [1] - 79:15 immediately [4] - 18:15, 119:1, 150:4, 150:9 imminent [1] - 25:1 immune [1] - 185:9 Impact [1] - 197:14 impact [1] - 183:21 impacted [1] - 194:20 impeaches [1] - 165:9 impeachment [2] - 146:23, 229:20 impermissible [1] - 39:17 implement [2] - 148:5, 220:15 implemented [1] - 210:12 implied [1] - 106:17 important [13] - 30:3, 37:3, 37:4, 37:7, 38:25, 39:12, 79:2, 118:3, 131:19, 148:17, 184:11, 188:3, 226:1 importantly [1] - 147:1 importers [1] - 16:21 impose [1] - 183:21 imposed [1] - 184:13 improper [8] - 51:25, 74:9, 91:20, 130:11, 146:23, 188:9, 221:8, 246:4 improperly [4] - 128:13, 129:11, 129:15, 246:4 improvement [1] - 276:21 IN [2] - 1:1, 1:18 in-depth [1] - 94:16 in-house [1] - 15:12 inaccuracy [1] - 63:5 Inc [1] - 39:5 incident [2] - 129:17, 158:23 include [12] - 123:4, 123:6, 123:14, 156:7, 156:11, 168:19, 169:3,
---	---	---	--	---

<p>194:5, 216:25, 272:5, 272:19, 273:11 included [6] - 37:21, 73:11, 175:7, 243:11, 251:3, 272:12 includes [5] - 123:5, 159:22, 168:11, 273:6, 273:8 including [8] - 141:24, 183:2, 193:11, 195:2, 203:17, 203:21, 206:6, 237:14 Including [3] - 177:8, 177:10, 177:11 incomplete [2] - 249:22, 272:14 inconsistent [7] - 108:8, 165:7, 187:13, 187:15, 187:23, 221:12, 221:14 incorporate [2] - 114:18, 248:2 incorporated [1] - 275:6 increase [9] - 55:8, 57:2, 94:16, 94:19, 184:25, 242:18, 248:3, 277:3, 277:13 increased [6] - 181:19, 191:11, 242:4, 243:25, 244:9, 244:12 increases [1] - 248:10 increasing [3] - 106:8, 243:22, 244:17 increment [1] - 57:5 Indeed [1] - 172:9 independent [3] - 106:18, 126:8, 130:4 independently [1] - 206:20 indicate [8] - 45:7, 45:8, 45:13, 58:16, 61:5, 86:6, 242:10, 242:12 indicated [1] - 43:14 indicating [1] - 196:12 indication [3] - 23:7, 59:6, 77:1 indicative [1] - 58:22 indicted [1] - 129:24 indirectly [1] - 261:15 individual [11] - 55:25, 92:23, 94:2, 149:3, 149:4, 149:11, 149:12, 164:12,</p>	<p>164:24, 176:7, 176:24 individually [2] - 109:1, 227:25 individuals [3] - 50:11, 54:20, 58:2 indulge [1] - 60:20 indulged [1] - 65:18 industrial [1] - 180:15 industry [3] - 39:13, 41:8, 259:11 Industry [2] - 41:3, 260:14 infers [1] - 260:7 inform [1] - 249:15 informants [1] - 16:8 information [26] - 20:12, 20:13, 20:24, 23:9, 24:11, 26:7, 26:8, 26:18, 26:20, 28:21, 38:17, 51:7, 76:11, 117:11, 120:7, 122:12, 122:17, 124:17, 141:3, 149:10, 191:8, 239:19, 249:22, 253:15, 261:4, 261:5 informed [4] - 126:10, 255:10, 255:12, 260:19 ingredient [11] - 67:16, 67:22, 67:25, 68:7, 69:9, 69:23, 70:11, 71:9, 71:20, 73:13, 75:21 initial [10] - 77:23, 142:1, 214:16, 215:4, 227:13, 227:14, 227:21, 227:22, 228:23, 230:9 initiated [1] - 41:18 initiative [2] - 253:6, 254:6 input [1] - 178:5 inquire [2] - 147:16, 170:12 inside [4] - 56:19, 75:16, 83:7, 94:24 inspection [4] - 20:14, 20:15, 20:20, 217:13 inspections [2] - 168:8, 201:11 Inspector [1] - 179:20 instance [5] - 69:8, 129:8, 149:14, 149:25, 205:8 instead [10] - 8:8, 29:15, 89:21, 204:8,</p>	<p>222:11, 232:18, 233:3, 239:16, 247:8, 247:14 Institute [1] - 126:14 institutes [1] - 77:19 Insys [4] - 146:17, 146:19, 148:4, 148:5 intact [1] - 270:11 integrate [1] - 276:12 intend [1] - 14:18 intending [2] - 67:1, 67:13 interacted [1] - 149:15 interest [1] - 251:22 interesting [2] - 37:25, 39:6 internal [7] - 8:25, 28:13, 42:20, 76:10, 76:11, 200:13, 200:14 internet [3] - 22:25, 39:7 interpose [1] - 50:24 interpret [1] - 78:3 interpretation [5] - 257:21, 260:15, 260:19, 261:1, 261:20 interrupt [5] - 22:9, 45:20, 62:8, 70:4, 91:10 interview [2] - 27:18, 36:14 interviewed [5] - 140:10, 140:16, 141:1, 141:2, 141:7 interviews [12] - 19:5, 20:25, 23:11, 26:20, 28:4, 28:7, 36:13, 143:18, 169:20, 169:22, 171:18 introduce [1] - 10:21 introduced [1] - 51:2 introducing [1] - 51:25 introduction [1] - 14:17 investigate [2] - 17:16, 18:9 investigated [6] - 19:5, 25:16, 128:17, 228:13, 228:17, 228:24 investigating [4] - 161:4, 161:7, 161:22, 162:2 investigation [35] - 16:10, 18:16, 19:22, 20:9, 20:19, 21:20, 21:23, 22:6, 22:8,</p>	<p>22:14, 22:17, 22:21, 23:13, 23:14, 24:10, 33:19, 34:16, 35:18, 41:18, 42:9, 42:17, 46:10, 46:13, 76:10, 76:17, 128:22, 161:12, 161:15, 162:6, 162:10, 168:21, 169:5, 169:14, 206:18, 256:4 Investigations [2] - 11:16, 11:24 investigations [21] - 11:19, 16:9, 17:13, 17:18, 18:2, 18:6, 18:7, 18:11, 18:13, 19:7, 22:4, 26:23, 30:10, 81:4, 161:17, 166:24, 168:2, 182:5, 201:13, 228:18 investigative [3] - 30:13, 176:20, 275:12 investigator [18] - 15:7, 16:1, 16:3, 22:11, 25:17, 36:16, 46:14, 46:15, 83:11, 160:1, 172:9, 253:16, 253:21, 254:25, 255:4, 256:5, 256:10, 259:22 investigators [7] - 38:2, 114:25, 159:11, 171:18, 255:23, 260:11, 260:12 invitation [1] - 12:4 involve [1] - 195:25 involved [8] - 37:23, 129:23, 182:17, 185:23, 253:18, 258:25, 259:1, 272:11 involving [2] - 143:2, 195:24 Iowa [1] - 209:1 ipsa [1] - 147:13 IRPINO [2] - 262:15, 262:21 Irpino [2] - 3:7, 262:21 ISIA [1] - 5:4 issue [33] - 26:14, 51:17, 76:6, 77:10, 125:20, 126:4, 140:20, 141:15, 141:16, 142:16, 158:8, 159:19,</p>	<p>164:11, 164:23, 169:6, 170:15, 171:13, 173:3, 182:6, 182:18, 183:8, 185:6, 196:19, 198:15, 199:17, 201:24, 202:3, 212:4, 213:3, 237:20, 245:25, 260:22, 265:2 issued [6] - 130:7, 132:9, 147:15, 156:22, 157:1, 157:24 issues [9] - 11:20, 18:8, 122:21, 125:19, 171:22, 205:6, 237:21, 238:13 issuing [3] - 20:13, 132:13, 160:19 item [1] - 148:3 items [2] - 34:10, 43:2 iteration [6] - 58:8, 58:9, 59:25, 60:2, 62:21, 65:4 iterations [2] - 54:15, 57:24</p>
J				
<p>Jackson [1] - 6:8 James [4] - 10:4, 10:7, 10:19, 10:23 JAMES [1] - 10:9 January [5] - 191:25, 231:6, 253:3, 254:12, 255:1 JASIEWICZ [1] - 5:4 JEFFREY [1] - 5:13 JENNIFER [1] - 4:12 job [7] - 12:22, 15:3, 15:20, 15:25, 16:9, 16:14, 240:7 Joe [1] - 123:6 join [8] - 14:5, 52:6, 53:8, 65:23, 74:6, 111:7, 112:15 joined [3] - 11:1, 14:25, 111:11 joint [1] - 12:3 joke [1] - 166:14 joking [1] - 115:14 JOSEPH [1] - 6:4 Joseph [2] - 121:11, 268:25 JR [2] - 2:3, 2:15 Juan [2] - 2:5, 2:17 Judge [37] - 7:2, 7:11, 8:1, 10:3, 13:4,</p>				

14:16, 15:2, 16:17, 18:12, 19:25, 22:20, 24:9, 25:5, 27:7, 27:10, 29:15, 30:8, 33:16, 34:4, 34:18, 42:1, 42:25, 44:3, 60:16, 64:6, 68:20, 72:19, 74:25, 82:11, 87:7, 91:22, 98:25, 146:22, 166:2, 197:8, 197:21, 265:7 judge [33] - 16:17, 44:24, 47:13, 47:18, 50:21, 56:17, 57:4, 58:14, 59:19, 65:14, 66:18, 74:2, 81:9, 82:8, 82:18, 85:23, 86:5, 87:15, 87:19, 89:10, 92:3, 93:8, 94:22, 99:25, 104:1, 113:7, 113:11, 157:6, 217:10, 221:8, 233:21, 255:18, 255:22 JUDGE [1] - 1:17 judgment [4] - 116:22, 179:13, 179:15, 242:24 judgments [2] - 117:9, 117:14 judicial [3] - 119:16, 202:19, 256:14 judicially [1] - 203:2 July [3] - 231:21, 231:25, 232:18 jump [2] - 14:24, 77:9 June [2] - 22:19, 267:13 jurisdiction [3] - 9:13, 136:21, 210:6 jurisdictions [2] - 145:18, 208:19 Justice [1] - 118:21 justification [1] - 94:17	181:19, 181:20 kind [15] - 12:22, 15:20, 28:15, 36:24, 75:12, 92:11, 119:4, 129:4, 160:13, 161:1, 161:25, 162:5, 237:1, 249:21, 260:7 kinds [2] - 17:7, 204:12 knowledge [15] - 27:20, 126:8, 130:4, 135:22, 135:23, 144:21, 156:25, 157:2, 158:1, 170:5, 171:15, 179:11, 224:14, 265:5, 265:11 known [4] - 112:4, 112:23, 210:24, 210:25 KOUBA [1] - 3:14 Kyle [4] - 174:14, 175:4, 258:22, 259:7	lawfully [2] - 269:11, 269:16 laws [2] - 149:6, 149:8 Lawson [1] - 265:7 lawsuit [1] - 223:20 lawyer [2] - 25:24, 277:24 lawyers [18] - 13:24, 116:1, 116:5, 116:8, 145:3, 145:8, 154:9, 154:16, 155:7, 155:13, 186:10, 188:10, 188:14, 188:17, 189:4, 189:10, 189:14, 223:22 lay [4] - 11:5, 53:1, 174:13, 277:4 lay-offs [1] - 11:5 layers [1] - 263:22 LDMP [1] - 274:24 lead [5] - 13:21, 22:10, 125:19, 208:1, 208:4 leaders [1] - 19:12 leading [4] - 65:18, 65:20, 65:24, 91:19 leads [1] - 29:17 leak [1] - 104:5 learned [1] - 272:10 least [7] - 13:13, 51:22, 126:17, 144:12, 146:12, 215:13, 215:20 leave [3] - 99:14, 136:19, 187:24 leaving [2] - 12:25, 21:12 led [9] - 12:3, 20:13, 20:25, 39:10, 90:7, 91:19, 91:23, 206:17, 218:19 Lee [1] - 3:12 left [26] - 11:5, 21:7, 43:2, 47:24, 49:7, 49:18, 56:23, 58:3, 58:17, 58:20, 61:6, 93:9, 96:20, 119:2, 120:9, 124:6, 139:7, 139:12, 139:13, 140:7, 142:22, 152:15, 163:16, 163:21, 192:13, 195:16 left-hand [7] - 120:9, 139:7, 139:12, 139:13, 140:7, 152:15, 192:13 legal [11] - 35:9, 106:17, 107:12, 108:8, 109:22,	111:4, 134:22, 151:8, 151:11, 176:20, 268:7 legitimacy [1] - 154:23 legitimate [19] - 116:22, 117:9, 117:13, 117:14, 117:17, 117:20, 120:24, 121:5, 121:15, 132:9, 148:18, 194:6, 196:8, 216:16, 216:20, 218:12, 242:4, 244:17, 244:21 legitimately [7] - 127:24, 183:15, 184:8, 195:10, 196:4, 198:19, 242:24 length [1] - 159:7 lengthy [1] - 143:21 Leo [1] - 18:17 Leon [2] - 2:4, 2:16 less [14] - 43:13, 153:8, 153:9, 153:14, 184:8, 184:23, 216:7, 216:9, 231:21, 242:24, 248:16, 250:7, 250:20, 274:12 letter [4] - 37:25, 85:20, 94:21, 269:6 letters [7] - 37:7, 39:2, 41:11, 252:24, 266:9, 268:16, 268:20 Level [2] - 106:24 level [10] - 12:1, 18:9, 18:11, 89:19, 135:11, 151:3, 179:6, 243:21, 243:25, 272:5 levels [8] - 16:24, 143:4, 196:24, 242:23, 246:5, 248:4, 248:5, 249:18 Levin [1] - 2:12 lexicon [1] - 93:8 LEYIMU [1] - 4:8 liability [4] - 171:1, 171:20, 172:11, 251:21 license [2] - 170:25, 171:19 licensed [6] - 131:9, 131:22, 133:18, 133:22, 144:5, 157:21	licenses [2] - 131:15, 171:22 licensing [3] - 18:8, 131:18, 170:20 licensure [1] - 150:9 lieutenant [2] - 12:10, 18:17 Lieutenant [1] - 12:15 life [1] - 218:7 Lifestyle [1] - 274:8 light [3] - 56:8, 56:21 likeliness [1] - 217:18 likely [16] - 24:23, 32:12, 104:8, 104:12, 112:5, 112:24, 130:6, 130:12, 153:14, 203:25, 214:11, 214:12, 216:15, 217:11, 222:22, 223:3 likewise [1] - 34:11 limit [12] - 67:17, 67:22, 67:25, 68:8, 69:9, 69:23, 70:11, 73:13, 75:21, 239:12, 271:24, 272:25 limited [3] - 39:21, 119:21, 272:24 limits [2] - 183:21, 184:13 LINDA [1] - 4:5 Linden [3] - 38:24, 38:25, 39:3 Line [1] - 229:14 line [14] - 91:16, 93:18, 112:17, 133:7, 167:1, 167:5, 167:14, 186:21, 187:16, 188:2, 188:23, 188:25, 194:10 Lines [2] - 212:22, 228:22 lines [6] - 112:12, 157:12, 164:17, 164:19, 186:19, 193:25 liquids [2] - 17:1, 21:9 Lisa [2] - 6:18, 278:19 List [3] - 38:13, 38:19, 38:20 list [20] - 27:13, 28:19, 35:16, 35:20, 36:23, 41:23, 42:22, 70:19, 70:22, 71:3, 72:7, 73:3, 94:25, 95:1, 138:17, 158:8, 158:16, 224:23,
L				
LA [1] - 3:8 labeled [1] - 273:9 labels [1] - 54:5 lack [2] - 89:4, 169:23 Lane [1] - 152:16 language [2] - 132:14, 143:9 Lanier [1] - 3:4 large [8] - 19:1, 20:10, 24:19, 84:2, 135:14, 136:3, 245:5, 271:12 larger [1] - 219:24 last [20] - 31:15, 48:25, 63:6, 64:5, 89:19, 90:8, 90:15, 101:7, 133:7, 168:5, 172:8, 191:25, 197:24, 198:10, 203:5, 203:13, 214:18, 231:17, 261:18, 277:16 launched [1] - 125:6 LAURA [1] - 5:10 law [19] - 10:24, 16:5, 32:4, 32:5, 78:21, 117:3, 117:5, 117:7, 121:6, 131:20, 156:4, 177:16, 191:3, 200:6, 201:7, 249:13, 249:24, 250:3, 269:22 Law [3] - 3:4, 3:7, 3:12 lawful [1] - 180:15				
K				
KEARSE [2] - 4:2, 278:4 keep [6] - 164:12, 164:24, 183:22, 208:3, 270:5, 270:11 keeps [1] - 207:25 Kelly [1] - 6:8 Kessler [1] - 4:17 key [2] - 76:6, 193:23 keys [1] - 193:23 killers [1] - 199:14 kilograms [2] -				

<p>265:25, 268:16 listed [4] - 42:10, 56:22, 103:8, 180:25 listen [1] - 137:2 lists [2] - 194:13, 271:4 lit [1] - 86:11 litigation [13] - 57:16, 59:1, 83:9, 85:14, 102:5, 102:20, 174:15, 190:2, 222:12, 222:14, 223:13, 223:20, 239:17 live [1] - 90:15 LLC [1] - 2:4 locate [2] - 164:6, 164:8 located [4] - 11:2, 11:7, 22:7, 129:19 locations [1] - 136:6 Logan [2] - 6:5, 6:12 logical [2] - 125:18, 144:21 logo [2] - 21:17, 197:12 long-standing [1] - 159:14 long-term [1] - 26:14 look [87] - 13:22, 20:17, 26:18, 26:19, 28:9, 28:13, 28:23, 29:2, 57:17, 67:15, 68:2, 76:10, 83:13, 83:15, 87:20, 87:24, 89:14, 90:19, 92:8, 118:8, 118:20, 119:22, 123:11, 123:16, 124:7, 125:1, 126:1, 128:2, 140:6, 140:22, 141:18, 151:17, 152:4, 157:12, 162:21, 163:17, 163:21, 169:16, 172:8, 175:10, 175:18, 175:23, 176:12, 176:23, 178:25, 179:11, 180:1, 180:7, 181:2, 181:8, 182:2, 182:21, 183:5, 184:21, 185:22, 186:11, 186:12, 191:17, 192:12, 193:23, 195:2, 200:22, 202:10, 206:19, 207:10, 214:24, 215:1, 215:16, 226:12,</p>	<p>229:13, 240:24, 243:15, 246:22, 247:7, 252:6, 259:6, 262:1, 264:5, 264:12, 267:20, 269:6, 269:8, 272:6, 277:4 looked [25] - 21:18, 23:3, 23:5, 48:13, 86:2, 86:3, 102:24, 109:16, 118:8, 121:16, 124:15, 124:16, 126:9, 153:10, 153:13, 195:20, 215:9, 218:16, 218:17, 218:24, 227:13, 227:21, 228:1, 243:24 looking [52] - 16:11, 22:15, 24:11, 26:13, 41:2, 45:6, 51:13, 54:23, 56:8, 56:12, 58:15, 58:20, 66:18, 66:23, 71:12, 82:5, 83:2, 84:2, 84:6, 84:20, 85:1, 90:14, 120:9, 127:19, 134:12, 140:8, 153:12, 166:12, 175:12, 176:9, 179:4, 179:23, 179:24, 182:21, 191:20, 192:12, 192:18, 235:15, 240:9, 240:11, 254:14, 254:15, 254:21, 255:4, 261:3, 261:4, 263:1, 267:13, 272:7, 272:10, 277:1 looks [6] - 23:24, 88:4, 89:12, 173:18, 205:9 lost [1] - 187:21 low [1] - 82:20 lower [12] - 17:23, 120:9, 126:1, 137:7, 139:7, 140:6, 142:22, 163:16, 163:21, 192:13, 273:20 Luken [5] - 151:3, 151:20, 152:13, 152:18, 153:3 Luken's [1] - 151:14</p>	<p>mailed [3] - 64:22, 64:23, 64:24 Mainigi [7] - 14:4, 30:25, 31:8, 52:4, 65:16, 68:15, 109:19 MAINIGI [27] - 4:12, 14:1, 14:5, 25:13, 31:1, 31:15, 35:7, 45:19, 46:12, 52:6, 53:8, 62:23, 65:17, 68:16, 68:19, 69:14, 73:23, 76:22, 78:19, 85:18, 86:2, 86:13, 108:7, 109:20, 111:3, 111:7, 112:8 maintain [7] - 24:13, 30:19, 30:21, 32:11, 107:9, 148:6, 164:8 maintained [8] - 30:1, 107:4, 107:22, 108:4, 108:15, 110:7, 135:2, 270:1 maintaining [2] - 23:20, 28:19 maintenance [6] - 30:11, 76:5, 146:7, 233:8, 251:18, 270:4 MAJESTRO [1] - 2:6 Majestro [1] - 2:6 major [1] - 18:6 majority [6] - 11:21, 117:23, 120:23, 121:4, 269:10, 269:15 Mallinckrodt [1] - 85:13 management [5] - 20:3, 20:21, 23:10, 26:10, 142:13 manager [1] - 166:13 mandates [1] - 267:22 manner [2] - 121:5, 245:7 manpower [1] - 12:2 manual [4] - 38:2, 38:4, 167:2, 274:5 Manual [2] - 38:15, 38:18 manuals [1] - 277:4 manufacture [3] - 38:14, 38:21, 180:11 manufactured [1] - 144:22 manufacturer [3] - 143:3, 145:20, 146:12 manufacturers [25] - 16:23, 16:24, 16:25, 116:9, 137:22, 138:8, 144:4,</p>	<p>144:12, 144:15, 144:22, 144:24, 145:12, 145:19, 145:23, 146:2, 148:13, 155:23, 178:6, 180:12, 181:15, 185:13, 186:24, 193:14, 194:16 manufactures [1] - 37:17 Mapes [4] - 260:3, 260:13, 260:19, 263:6 March [1] - 264:11 marijuana [1] - 12:7 MARK [1] - 3:16 mark [1] - 274:1 marked [7] - 37:15, 118:13, 124:22, 173:16, 256:8, 278:6, 278:8 market [16] - 30:12, 104:9, 107:5, 107:23, 108:5, 108:17, 110:8, 111:1, 111:21, 112:5, 112:25, 138:8, 141:22, 178:7, 178:9, 260:18 marketed [1] - 140:10 marketing [3] - 141:3, 141:21, 142:11 Masters [36] - 22:6, 22:11, 22:14, 22:21, 24:22, 27:14, 28:6, 28:10, 40:24, 85:5, 85:9, 87:17, 96:13, 225:13, 225:16, 225:18, 225:20, 225:21, 225:25, 235:3, 235:5, 235:6, 236:8, 236:20, 236:25, 237:22, 238:15, 238:19, 239:15, 240:19, 246:9, 266:14, 266:18, 267:12, 268:5, 269:3 material [7] - 16:22, 34:5, 59:7, 102:23, 182:9, 254:21, 266:19 materials [20] - 14:20, 14:21, 33:20, 33:23, 34:15, 35:17, 36:18, 36:19, 36:24, 37:12, 41:17, 41:23, 42:5, 42:10, 50:10, 102:8, 188:19, 265:25,</p>	<p>268:17, 268:21 math [2] - 212:10, 250:4 matter [11] - 30:14, 34:18, 86:8, 128:2, 134:4, 142:2, 142:3, 158:9, 170:17, 233:7, 278:21 matters [2] - 151:9, 151:11 maximum [10] - 85:3, 85:7, 87:18, 93:22, 93:25, 95:13, 100:19, 101:8, 180:9, 247:22 MAY [1] - 1:19 Mays [1] - 54:5 MC-WV-1764 [1] - 138:19 MC-WV-2096 [1] - 197:11 McCann [38] - 13:15, 51:2, 51:10, 51:20, 52:11, 52:19, 52:24, 53:17, 53:18, 96:6, 96:7, 114:9, 114:10, 114:13, 114:16, 115:5, 137:2, 150:18, 152:6, 152:11, 201:17, 210:13, 210:16, 210:21, 212:2, 212:13, 212:23, 213:8, 213:16, 220:19, 220:21, 221:21, 222:1, 227:5, 230:12, 231:5, 244:23 McCann's [10] - 13:16, 114:20, 150:13, 151:25, 154:6, 202:3, 212:2, 212:19, 212:21, 273:9 MCCLURE [1] - 6:3 MCGINNESS [1] - 4:2 McKesson [59] - 5:8, 7:20, 8:7, 8:16, 8:25, 14:8, 29:24, 45:7, 47:22, 49:6, 49:18, 49:21, 49:23, 51:18, 51:22, 58:13, 60:2, 63:6, 73:21, 96:19, 97:4, 98:2, 98:10, 98:22, 100:13, 101:3, 101:18, 102:11, 105:18, 105:19, 106:4, 106:7, 106:12, 106:24, 108:15,</p>
<p style="text-align: center;">M</p>				
<p>Magazine [1] - 3:7 MAHADY [1] - 6:4</p>				

<p>109:1, 129:9, 130:9, 130:14, 130:18, 130:22, 131:7, 131:21, 150:24, 151:23, 206:6, 206:9, 206:13, 207:3, 219:11, 227:14, 227:22, 230:22, 250:25, 251:14, 271:6, 273:23, 277:5</p> <p>McKesson's [3] - 106:2, 137:6, 273:17</p> <p>MCWV-2096 [1] - 199:9</p> <p>MDL [1] - 146:21</p> <p>mean [12] - 25:10, 45:19, 62:8, 66:1, 69:24, 91:10, 102:21, 109:14, 109:17, 255:23, 255:25, 273:12</p> <p>meaning [1] - 169:10</p> <p>meaningful [1] - 132:21</p> <p>means [10] - 43:18, 69:8, 77:15, 79:18, 79:21, 93:8, 227:10, 243:5, 273:12, 277:24</p> <p>meant [5] - 35:4, 61:6, 153:16, 153:18, 261:10</p> <p>measure [1] - 72:6</p> <p>measures [2] - 269:11, 269:16</p> <p>measuring [2] - 55:20, 55:22</p> <p>mechanical [1] - 6:19</p> <p>mechanism [1] - 81:24</p> <p>medical [28] - 17:7, 116:16, 116:22, 117:9, 117:13, 117:14, 120:24, 121:15, 122:23, 129:5, 132:9, 149:11, 170:24, 171:24, 180:14, 180:20, 180:24, 195:13, 196:8, 216:17, 216:20, 216:24, 217:1, 218:12, 218:17, 241:23, 242:3, 244:17</p> <p>medication [6] - 183:15, 184:14, 184:18, 196:7, 217:7, 218:4</p>	<p>medications [4] - 48:13, 148:13, 184:11, 218:8</p> <p>Medicine [4] - 67:5, 70:22, 71:25, 72:22</p> <p>medicine [1] - 196:6</p> <p>meet [5] - 19:13, 43:17, 84:10, 205:13, 216:8</p> <p>meeting [1] - 181:3</p> <p>meetings [1] - 21:24</p> <p>meets [1] - 43:24</p> <p>members [1] - 198:18</p> <p>memo [3] - 38:24, 39:1, 39:4</p> <p>Memorandum [3] - 22:1, 22:23, 23:3</p> <p>memorize [1] - 215:15</p> <p>memory [1] - 152:4</p> <p>memos [1] - 42:21</p> <p>mention [3] - 62:25, 126:16, 143:23</p> <p>mentioned [5] - 130:17, 130:24, 131:1, 136:16, 240:1</p> <p>mentions [1] - 260:2</p> <p>mess [1] - 87:8</p> <p>met [1] - 38:7</p> <p>methadone [1] - 176:8</p> <p>Methamphetamine [1] - 38:9</p> <p>methamphetamine [2] - 38:14, 38:23</p> <p>method [7] - 215:14, 231:24, 239:1, 240:15, 246:13, 247:6, 250:8</p> <p>Method [48] - 219:6, 219:10, 219:11, 219:13, 219:16, 225:25, 226:4, 226:6, 226:8, 226:9, 226:15, 226:16, 226:17, 227:5, 227:15, 227:23, 228:23, 230:6, 231:9, 235:2, 236:13, 236:17, 237:3, 237:8, 237:14, 237:20, 237:24, 238:6, 238:14, 238:19, 238:23, 241:1, 241:8, 241:9, 242:22, 245:10, 245:19, 246:17, 246:19, 246:21, 278:8</p> <p>methodical [1] - 82:11</p> <p>methodological [1] -</p>	<p>147:10</p> <p>methodologically [2] - 99:5, 190:9</p> <p>methodologies [45] - 81:22, 82:2, 84:21, 84:22, 87:15, 95:22, 96:1, 114:3, 114:5, 114:10, 114:13, 199:20, 199:21, 208:13, 208:15, 210:12, 210:13, 212:11, 212:14, 213:10, 213:17, 214:14, 216:23, 220:8, 220:9, 220:11, 220:14, 222:6, 222:11, 222:16, 222:21, 222:25, 223:2, 223:6, 223:7, 223:11, 224:23, 225:1, 225:6, 226:6, 228:13, 239:13, 240:16, 240:22, 241:7</p> <p>methodology [46] - 14:19, 22:8, 26:23, 27:2, 27:5, 30:18, 32:17, 36:9, 44:8, 53:2, 85:20, 86:8, 87:16, 89:20, 90:8, 91:8, 92:4, 92:24, 93:6, 95:10, 96:11, 98:12, 98:15, 99:22, 100:18, 100:20, 101:7, 111:9, 114:3, 115:24, 214:6, 215:10, 227:3, 232:15, 232:21, 235:4, 237:3, 237:8, 237:10, 237:13, 240:25, 242:2, 243:4, 247:18, 248:2, 249:18</p> <p>Methodology [5] - 89:17, 90:9, 90:14, 229:10</p> <p>methods [15] - 219:5, 225:2, 225:8, 239:4, 239:5, 240:4, 244:15, 244:16, 244:18, 245:1, 245:6, 245:10, 246:16, 246:19, 250:15</p> <p>metric [2] - 65:8, 86:10</p> <p>metrics [1] - 87:1</p> <p>Metropolitan [1] - 11:10</p>	<p>Miami [6] - 151:3, 151:14, 151:20, 152:13, 152:18, 153:3</p> <p>Miami-Luken [5] - 151:3, 151:20, 152:13, 152:18, 153:3</p> <p>Miami-Luken's [1] - 151:14</p> <p>Michael [3] - 260:3, 260:13, 263:6</p> <p>MICHAEL [2] - 2:15, 3:9</p> <p>Michigan [7] - 11:2, 11:5, 11:8, 15:17, 17:24, 128:17</p> <p>microphone [1] - 90:5</p> <p>middle [3] - 58:4, 163:22, 163:23</p> <p>midnight [2] - 12:11, 86:3</p> <p>might [21] - 37:10, 110:19, 122:18, 125:24, 136:8, 157:13, 157:24, 158:13, 158:18, 161:24, 183:21, 183:22, 192:17, 204:17, 220:22, 240:3, 240:16, 246:12, 252:4, 252:10, 258:25</p> <p>MILDRED [1] - 3:3</p> <p>miles [1] - 11:8</p> <p>military [1] - 18:18</p> <p>mill [14] - 18:20, 18:21, 19:9, 20:4, 128:16, 130:10, 130:19, 156:23, 157:1, 157:17, 157:22, 157:25, 158:2, 167:23</p> <p>milligrams [4] - 18:25, 71:5, 71:9</p> <p>million [1] - 122:9</p> <p>millions [6] - 214:7, 214:11, 228:5, 229:8, 229:15, 229:25</p> <p>mindful [1] - 31:24</p> <p>mine [1] - 115:20</p> <p>minimally [1] - 187:9</p> <p>minimum [1] - 186:13</p> <p>minus [3] - 272:8, 272:9</p> <p>minute [5] - 72:10, 81:1, 190:20, 220:1, 263:17</p> <p>minutes [7] - 25:25,</p>	<p>113:12, 162:3, 167:21, 199:3, 270:19, 270:22</p> <p>mischaracterization [1] - 154:16</p> <p>misconduct [1] - 171:23</p> <p>misconstruing [1] - 233:24</p> <p>misheard [1] - 187:16</p> <p>misleading [1] - 68:23</p> <p>missed [4] - 15:25, 103:17, 105:5, 109:17</p> <p>missing [5] - 266:12, 271:12, 271:16, 271:18, 271:21</p> <p>mission [1] - 29:4</p> <p>misstating [1] - 90:7</p> <p>misunderstood [3] - 110:19, 153:16, 229:24</p> <p>misuse [3] - 196:13, 198:11, 199:14</p> <p>misuses [1] - 196:7</p> <p>Mitchell [1] - 2:12</p> <p>mixed [1] - 90:8</p> <p>modified [1] - 240:18</p> <p>moment [3] - 47:17, 113:7, 190:25</p> <p>Mone [3] - 58:4, 233:15, 234:15</p> <p>Mone's [2] - 233:24, 234:8</p> <p>monitor [5] - 70:17, 75:14, 106:17, 183:13, 187:22</p> <p>monitored [1] - 59:2</p> <p>Monitoring [12] - 24:16, 27:23, 30:5, 30:10, 37:18, 41:3, 42:16, 58:9, 60:5, 75:12, 146:9, 220:15</p> <p>monitoring [9] - 59:8, 59:13, 60:10, 74:19, 82:23, 83:8, 87:25, 106:13, 256:21</p> <p>month [55] - 56:2, 58:23, 64:19, 68:11, 70:12, 70:22, 71:24, 72:4, 73:9, 77:21, 80:14, 80:21, 85:4, 85:7, 87:18, 87:24, 87:25, 88:1, 88:12, 88:21, 89:1, 89:2, 89:15, 90:16, 90:18, 92:6, 92:7, 92:12, 92:13, 92:16, 93:10, 93:19, 94:5, 94:6, 94:7, 100:19,</p>
--	--	---	--	---

<p>161:20, 230:15, 232:17, 233:4, 234:20, 236:25, 239:16, 243:21, 244:1, 247:1, 247:9, 276:6</p> <p>monthly [13] - 56:13, 61:9, 61:14, 69:3, 73:5, 85:3, 85:7, 87:12, 87:18, 92:9, 94:1, 95:10, 274:3</p> <p>months [40] - 68:6, 87:23, 88:1, 88:5, 88:8, 88:17, 89:19, 90:15, 90:19, 92:3, 92:7, 92:8, 92:17, 98:14, 231:4, 231:10, 231:15, 231:16, 231:17, 231:18, 231:20, 231:21, 232:10, 232:25, 233:3, 233:5, 234:21, 238:20, 243:11, 245:18, 246:6, 246:10, 246:22, 246:24, 247:7, 247:8, 247:15, 274:12, 276:5</p> <p>morning [8] - 7:6, 8:8, 10:13, 10:17, 10:23, 81:12, 278:3, 278:13</p> <p>Morris [1] - 6:15</p> <p>most [12] - 19:21, 24:6, 30:2, 55:17, 99:4, 182:15, 183:1, 215:9, 215:20, 215:24, 219:7, 244:12</p> <p>motion [7] - 30:17, 30:22, 32:3, 107:18, 166:4, 234:11</p> <p>Motley [5] - 2:9, 3:14, 4:3, 4:5, 4:8</p> <p>MOU [1] - 23:2</p> <p>MOUGEY [1] - 2:12</p> <p>mouthpiece [1] - 188:9</p> <p>move [24] - 7:11, 7:16, 8:6, 12:4, 13:3, 47:24, 58:12, 86:15, 86:25, 91:2, 91:5, 93:9, 119:10, 126:19, 127:12, 138:18, 165:23, 174:7, 192:3, 197:19, 229:21, 256:13, 264:3, 265:21</p> <p>moved [2] - 11:6,</p>	<p>231:4</p> <p>moving [7] - 20:23, 23:8, 34:22, 56:21, 58:3, 202:12, 267:6</p> <p>MR [378] - 2:3, 2:6, 2:9, 2:12, 2:15, 3:9, 3:11, 3:16, 4:17, 5:9, 5:10, 5:13, 6:4, 7:8, 7:11, 7:14, 7:19, 7:21, 7:25, 8:3, 8:4, 8:13, 8:14, 8:21, 9:9, 9:22, 9:24, 10:3, 10:16, 13:4, 13:11, 14:10, 14:15, 14:23, 21:19, 25:5, 25:6, 25:21, 25:25, 26:4, 27:7, 27:9, 30:8, 30:16, 31:3, 31:9, 32:10, 32:14, 32:19, 32:24, 32:25, 33:2, 33:6, 33:16, 33:18, 34:4, 34:13, 34:18, 34:21, 34:24, 35:3, 35:6, 35:13, 35:15, 36:5, 36:7, 36:20, 37:9, 39:15, 40:2, 40:9, 40:14, 40:17, 42:1, 42:6, 42:25, 43:6, 44:3, 44:5, 44:24, 45:2, 46:2, 46:17, 46:18, 47:13, 47:16, 50:21, 50:24, 51:9, 51:17, 52:10, 52:24, 53:6, 53:10, 53:22, 53:25, 59:19, 59:22, 59:23, 60:16, 60:19, 62:8, 62:11, 62:16, 62:17, 62:18, 63:5, 63:7, 63:14, 63:17, 64:4, 64:9, 65:10, 65:14, 65:23, 66:3, 66:5, 66:18, 66:22, 68:18, 68:20, 69:1, 69:2, 69:18, 69:21, 70:8, 70:10, 72:17, 72:19, 72:21, 73:18, 74:2, 74:6, 74:9, 74:15, 74:25, 75:7, 75:24, 76:21, 77:7, 78:1, 78:8, 78:22, 79:8, 79:9, 80:11, 81:9, 81:13, 81:16, 81:19, 82:8, 82:14, 85:23, 86:5, 86:23, 86:24, 87:6, 87:10, 89:25, 90:4, 90:13, 90:22, 90:24, 91:3, 91:4, 91:10, 91:12, 91:18, 91:22, 92:1, 92:2, 94:4, 96:8, 96:9, 99:3,</p>	<p>99:8, 99:13, 99:15, 99:16, 99:21, 100:17, 102:25, 103:2, 106:16, 106:22, 107:11, 107:14, 107:20, 108:10, 108:19, 108:22, 109:25, 110:4, 110:14, 110:17, 110:23, 111:5, 111:8, 111:11, 111:16, 112:10, 112:14, 112:15, 112:20, 112:21, 113:7, 113:11, 113:17, 113:24, 114:1, 115:7, 115:9, 115:13, 118:10, 118:12, 119:10, 119:13, 119:15, 119:19, 120:1, 120:4, 124:20, 124:21, 125:23, 125:24, 126:3, 126:19, 126:21, 126:24, 127:5, 127:7, 127:12, 127:15, 128:10, 138:18, 138:21, 138:23, 139:5, 139:10, 145:4, 145:7, 145:14, 146:22, 147:9, 147:19, 147:21, 152:10, 154:10, 154:18, 155:1, 155:4, 160:17, 161:2, 161:3, 165:3, 165:6, 165:10, 165:15, 165:23, 166:2, 166:7, 172:15, 172:17, 172:18, 172:21, 174:7, 174:10, 174:12, 174:20, 174:22, 178:12, 187:12, 187:16, 187:19, 188:1, 189:22, 189:25, 190:11, 190:12, 190:17, 190:20, 190:24, 192:3, 192:6, 192:8, 193:1, 193:4, 197:8, 197:10, 197:18, 197:21, 197:23, 197:25, 198:1, 198:3, 198:6, 199:1, 199:6, 199:7, 200:18, 200:24,</p>	<p>202:20, 202:21, 202:24, 203:1, 203:3, 207:11, 207:15, 207:17, 207:21, 209:4, 209:7, 211:23, 211:25, 214:1, 214:4, 214:5, 215:23, 215:25, 216:2, 217:21, 217:25, 218:25, 219:4, 221:8, 221:11, 221:17, 221:19, 221:22, 221:25, 230:21, 231:2, 232:3, 232:4, 233:17, 233:21, 233:23, 234:3, 234:5, 234:10, 234:11, 234:13, 234:14, 234:16, 234:18, 234:19, 235:13, 238:8, 238:12, 239:6, 243:14, 243:17, 246:14, 246:15, 256:12, 256:18, 262:15, 262:18, 262:21, 262:24, 263:15, 263:19, 263:20, 263:21, 264:3, 264:4, 267:5, 267:9, 267:11, 270:15, 270:21, 270:25, 277:11, 277:15, 277:17, 277:21, 277:25, 278:10</p> <p>MS [43] - 3:3, 3:6, 3:14, 4:2, 4:5, 4:8, 4:12, 4:12, 4:15, 5:3, 5:4, 5:10, 6:3, 6:7, 6:14, 7:22, 14:1, 14:5, 25:13, 31:1, 31:15, 35:7, 45:19, 46:12, 52:6, 53:8, 62:23, 65:17, 68:16, 68:19, 69:14, 73:23, 76:22, 78:19, 85:18, 86:2, 86:13, 108:7, 109:20, 111:3, 111:7, 112:8, 278:4</p> <p>Mt [3] - 3:15, 4:4, 4:9</p> <p>multi [2] - 232:6, 244:8</p> <p>multi-year [2] - 232:6, 244:8</p> <p>multiple [6] - 48:18, 119:8, 141:23, 164:6, 262:18,</p>	<p>263:21</p> <p>multiplied [1] - 98:14</p> <p>multiplier [1] - 86:1</p> <p>multiply [1] - 69:6</p> <p>multiplying [2] - 68:14, 99:23</p>
N				
<p>name [6] - 10:5, 10:17, 41:6, 144:23, 262:20, 274:5</p> <p>named [2] - 18:17, 125:21</p> <p>names [5] - 54:3, 54:10, 54:19, 56:19, 58:2</p> <p>narcotic [4] - 11:22, 16:22, 19:11, 69:25</p> <p>narcotics [2] - 16:25, 61:19</p> <p>narrative [1] - 39:22</p> <p>narrow [1] - 52:18</p> <p>Nassau [2] - 208:25, 209:12</p> <p>nation [1] - 92:19</p> <p>national [6] - 9:16, 93:2, 93:3, 106:24, 129:6, 180:5</p> <p>National [1] - 126:14</p> <p>nationally [3] - 9:4, 62:4, 141:9</p> <p>nationwide [2] - 207:9, 207:10</p> <p>nearby [1] - 204:18</p> <p>nearest [1] - 64:24</p> <p>nearly [2] - 166:15, 166:22</p> <p>necessarily [1] - 127:3</p> <p>necessary [3] - 132:9, 154:13, 180:11</p> <p>need [34] - 7:23, 7:24, 33:2, 43:16, 66:19, 68:24, 69:12, 72:8, 74:7, 81:11, 110:1, 116:16, 117:13, 120:6, 132:9, 149:11, 157:13, 176:17, 180:20, 183:20, 183:22, 184:7, 189:1, 216:17, 216:20, 216:24, 217:1, 218:12, 218:17, 218:25, 230:23, 233:12, 270:1</p> <p>needed [2] - 183:15, 184:14</p> <p>Needed [1] - 192:10</p> <p>needs [9] - 84:11,</p>				

<p>94:19, 116:22, 129:5, 180:15, 180:21, 180:25, 184:25, 241:24</p> <p>never [34] - 13:15, 51:2, 89:5, 97:14, 97:16, 121:6, 127:10, 133:8, 133:12, 146:12, 146:18, 151:23, 151:25, 157:18, 161:8, 189:10, 205:16, 220:17, 222:6, 222:9, 223:19, 236:16, 241:9, 241:13, 245:19, 247:2, 250:14, 251:14, 252:1, 253:10, 257:6, 257:18, 259:22, 277:24</p> <p>new [23] - 170:3, 205:15, 227:3, 237:3, 237:8, 237:10, 237:13, 239:1, 240:3, 241:1, 246:13, 251:2, 258:16, 260:15, 261:1, 261:20, 274:14, 274:16, 275:12, 275:17, 276:8, 276:15, 277:5</p> <p>New [8] - 3:5, 3:8, 157:6, 164:15, 173:19, 211:4, 211:18, 262:9</p> <p>next [49] - 10:2, 19:8, 36:6, 38:2, 38:6, 38:15, 38:24, 39:5, 41:21, 44:6, 48:1, 55:7, 56:16, 58:12, 59:18, 71:7, 81:17, 87:9, 91:2, 93:19, 94:21, 104:14, 105:17, 137:13, 140:22, 141:18, 163:21, 166:12, 167:17, 168:19, 169:17, 169:19, 170:8, 176:1, 181:14, 182:2, 183:5, 187:3, 189:1, 219:2, 231:15, 231:16, 232:5, 239:22, 247:1, 247:8, 256:24, 259:6, 268:4</p> <p>Next [1] - 16:23</p> <p>nice [1] - 29:17</p> <p>NICHOLAS [16] - 6:11,</p>	<p>14:10, 31:9, 32:19, 35:3, 50:24, 51:9, 53:6, 63:7, 65:23, 74:6, 78:22, 99:8, 107:11, 111:11, 112:15</p> <p>Nicholas [10] - 14:9, 31:7, 32:18, 35:2, 51:20, 51:23, 53:5, 65:22, 74:3, 99:7</p> <p>Ninth [1] - 4:6</p> <p>none [7] - 20:7, 195:25, 204:23, 216:3, 217:15, 220:14</p> <p>None [2] - 138:21, 192:6</p> <p>noon [1] - 113:14</p> <p>normal [5] - 82:25, 84:18, 117:12, 203:6, 245:4</p> <p>North [1] - 176:9</p> <p>northern [1] - 17:25</p> <p>notable [4] - 18:13, 19:7, 19:25, 22:4</p> <p>note [2] - 32:6, 57:23</p> <p>noted [2] - 267:20, 267:21</p> <p>nothing [1] - 264:11</p> <p>notice [6] - 119:16, 202:12, 202:19, 256:14, 267:7, 268:15</p> <p>noticed [1] - 203:2</p> <p>noting [2] - 86:15, 166:14</p> <p>November [1] - 197:24</p> <p>nowhere [1] - 204:6</p> <p>number [68] - 35:9, 36:12, 38:6, 46:4, 46:19, 46:23, 47:3, 47:18, 47:19, 47:20, 47:25, 48:2, 48:23, 48:24, 48:25, 49:1, 49:5, 49:7, 49:8, 49:9, 49:19, 49:20, 52:11, 56:17, 67:5, 68:8, 83:12, 83:24, 84:2, 85:20, 87:21, 87:22, 92:16, 103:23, 120:15, 125:23, 134:7, 134:8, 134:16, 137:7, 139:6, 139:7, 157:14, 157:15, 167:23, 187:2, 196:16, 196:17, 196:18, 216:21, 219:23, 229:7, 229:22, 245:5,</p>	<p>246:24, 247:2, 247:3, 247:15, 250:13, 271:1, 271:4, 272:1, 272:20, 277:14</p> <p>Number [2] - 180:2, 180:3</p> <p>numbered [1] - 180:1</p> <p>numbers [27] - 49:16, 83:15, 101:22, 103:11, 120:9, 126:1, 153:5, 153:12, 163:16, 179:24, 182:6, 182:19, 206:1, 206:2, 208:14, 208:16, 209:21, 209:22, 209:24, 210:9, 210:10, 226:20, 231:17, 250:21, 271:12, 273:20</p> <p>NW [6] - 2:10, 4:6, 4:13, 4:15, 5:5, 5:12</p> <p>NWDA [6] - 37:15, 37:16, 37:20, 37:24, 41:2, 41:4</p> <p>NY [1] - 3:5</p>	<p>86:20, 90:11, 91:23, 91:25, 106:16, 107:17, 108:7, 108:19, 111:3, 112:8, 112:10, 112:11, 112:17, 119:12, 138:20, 145:6, 154:25, 174:9, 174:20, 187:24, 192:5, 197:20, 197:25, 202:18, 207:11, 207:17, 209:4, 234:7, 239:6, 256:15, 262:22, 263:15, 264:2, 267:10</p> <p>objections [9] - 8:9, 9:25, 14:7, 74:6, 74:9, 110:1, 111:11, 111:14, 233:23</p> <p>objective [1] - 88:15</p> <p>objectors [1] - 262:19</p> <p>obligation [3] - 132:12, 155:19, 156:15</p> <p>obligations [6] - 134:22, 156:4, 156:7, 156:11, 199:22, 257:5</p> <p>observable [1] - 275:8</p> <p>observe [2] - 117:11, 259:4</p> <p>observed [1] - 53:16</p> <p>obtain [7] - 20:18, 23:23, 27:17, 28:9, 28:11, 172:1, 184:18</p> <p>obtained [6] - 23:12, 38:3, 38:4, 45:16, 195:10, 196:5</p> <p>obtaining [1] - 28:21</p> <p>obviously [4] - 182:14, 207:25, 208:3, 264:15</p> <p>Obviously [1] - 165:19</p> <p>occasion [3] - 118:9, 124:7, 251:9</p> <p>occur [9] - 104:13, 179:7, 189:16, 193:10, 194:1, 194:3, 194:18, 220:5, 220:7</p> <p>occurred [12] - 97:11, 135:11, 149:17, 153:2, 153:20, 158:2, 165:19, 190:2, 205:19, 212:8, 253:7, 273:24</p> <p>occurrence [1] - 158:21</p>	<p>occurring [5] - 135:24, 157:2, 208:8, 249:15, 272:4</p> <p>occurs [2] - 233:6, 248:10</p> <p>OF [2] - 1:1, 1:4</p> <p>offense [1] - 230:25</p> <p>offer [5] - 12:18, 12:19, 15:10, 185:20, 186:2</p> <p>offered [7] - 30:23, 31:4, 31:12, 31:16, 144:11, 237:13, 257:3</p> <p>offering [6] - 25:19, 32:8, 135:10, 144:24, 145:2, 185:15</p> <p>offers [1] - 12:21</p> <p>Office [6] - 21:24, 64:25, 121:11, 123:7, 138:13, 179:20</p> <p>office [14] - 15:17, 17:23, 18:21, 18:22, 19:13, 19:14, 39:1, 84:4, 164:14, 165:8, 167:8, 167:9, 170:21, 191:23</p> <p>officer [3] - 11:12, 16:5, 256:3</p> <p>Officer [2] - 12:5, 12:7</p> <p>officers [1] - 12:20</p> <p>Offices [1] - 64:23</p> <p>offices [3] - 164:13, 164:25, 166:21</p> <p>Official [2] - 278:18, 278:19</p> <p>official [4] - 22:15, 120:22, 126:24, 236:5</p> <p>officials [5] - 121:7, 140:11, 140:17, 141:2, 141:7</p> <p>offs [1] - 11:5</p> <p>often [3] - 28:6, 133:6, 166:23</p> <p>Ognen [3] - 18:17, 19:6, 128:16</p> <p>Ognen's [1] - 19:4</p> <p>Ohio [10] - 9:11, 17:25, 18:1, 18:19, 22:8, 128:18, 128:19, 209:16, 211:4, 211:20</p> <p>OIG [1] - 184:24</p> <p>old [1] - 12:24</p> <p>on-line [3] - 167:1, 167:5, 167:14</p> <p>on-site [5] - 22:22,</p>
--	--	---	---	---

<p>28:7, 28:10, 160:13, 169:11</p> <p>once [7] - 75:25, 77:12, 78:9, 81:5, 88:20, 96:14, 158:20</p> <p>Once [1] - 26:6</p> <p>One [7] - 5:11, 15:21, 21:6, 36:12, 120:13, 166:13, 174:3</p> <p>one [159] - 12:21, 13:13, 17:9, 22:10, 27:13, 27:16, 29:6, 31:5, 37:11, 38:22, 48:18, 51:13, 52:11, 53:1, 55:24, 56:2, 58:16, 58:23, 63:3, 64:14, 64:16, 64:19, 71:4, 71:12, 72:10, 73:25, 81:12, 82:15, 85:3, 85:12, 85:14, 85:16, 87:21, 91:6, 92:15, 92:25, 94:20, 95:2, 95:20, 102:23, 105:15, 109:17, 116:18, 118:1, 122:9, 122:10, 122:11, 122:15, 125:25, 129:14, 130:24, 131:1, 138:15, 139:22, 144:15, 146:12, 146:13, 146:14, 148:20, 149:14, 151:2, 156:10, 162:12, 171:15, 172:9, 172:10, 174:1, 176:17, 176:22, 179:11, 183:19, 186:1, 187:18, 190:15, 190:20, 194:9, 194:24, 195:1, 195:12, 195:23, 197:6, 198:17, 204:17, 206:21, 208:2, 209:20, 210:2, 210:6, 214:10, 214:16, 215:4, 216:13, 217:3, 219:24, 220:10, 222:18, 224:17, 225:8, 228:4, 228:16, 231:3, 232:17, 232:22, 232:24, 234:21, 238:10, 238:13, 238:19, 239:15, 239:18, 239:23, 241:6, 245:6, 246:19, 248:21, 249:8,</p>	<p>249:21, 249:23, 250:3, 251:7, 251:8, 257:21, 258:23, 259:7, 260:2, 260:5, 260:10, 261:8, 261:9, 261:11, 266:12, 266:13, 267:16, 268:14, 268:20, 270:3, 270:15, 270:17, 271:9, 273:23, 274:19, 274:20, 274:24, 275:10, 277:9, 277:19, 277:21, 277:24, 278:4, 278:5</p> <p>one-step [1] - 73:25</p> <p>ones [15] - 8:19, 8:21, 97:12, 134:17, 137:25, 138:5, 195:2, 195:25, 196:25, 197:7, 215:16, 218:17, 219:7, 239:14, 240:18</p> <p>ongoing [1] - 45:21</p> <p>open [7] - 20:23, 28:5, 204:18, 205:4, 224:15, 224:17, 235:12</p> <p>operated [3] - 29:3, 30:5, 109:2</p> <p>operating [1] - 274:5</p> <p>operationalize [1] - 213:9</p> <p>operations [2] - 20:4, 20:5</p> <p>opinion [56] - 32:16, 53:15, 53:19, 81:8, 107:3, 107:8, 107:15, 107:21, 108:1, 108:3, 108:11, 108:15, 108:23, 108:25, 109:6, 109:8, 109:11, 109:13, 110:6, 110:11, 110:24, 111:6, 111:17, 111:19, 111:24, 112:1, 112:3, 112:22, 113:2, 122:18, 128:2, 135:12, 136:21, 146:19, 147:12, 154:8, 155:6, 155:12, 155:15, 165:20, 182:16, 185:15, 188:20, 188:21, 189:15, 189:18,</p>	<p>189:19, 228:19, 259:25, 262:1, 262:25, 264:5, 265:18, 266:25, 268:9</p> <p>opinions [42] - 14:22, 32:1, 32:4, 32:6, 32:10, 43:3, 43:17, 43:25, 52:13, 113:4, 115:24, 135:10, 136:12, 136:15, 137:14, 138:16, 144:11, 144:24, 145:2, 145:22, 147:13, 155:11, 185:19, 185:20, 186:2, 188:13, 188:15, 188:16, 189:3, 189:11, 189:13, 190:1, 190:3, 190:4, 190:5, 216:4, 216:7, 218:4, 218:8, 218:12, 245:23</p> <p>opioid [28] - 56:9, 122:24, 123:1, 123:19, 124:12, 125:11, 125:16, 126:15, 133:17, 136:16, 136:22, 137:15, 137:20, 142:1, 144:13, 156:21, 157:21, 178:15, 181:11, 182:14, 184:25, 185:8, 185:12, 185:16, 185:21, 186:3, 186:14, 208:7</p> <p>Opioid [1] - 192:11</p> <p>opioids [50] - 20:7, 107:5, 107:23, 108:5, 108:17, 110:8, 111:1, 111:21, 116:17, 116:21, 116:23, 119:5, 121:15, 125:14, 125:17, 126:5, 127:19, 129:5, 131:12, 132:22, 133:21, 134:5, 134:12, 136:13, 137:23, 138:1, 138:9, 144:4, 144:8, 144:16, 148:19, 154:5, 156:9, 156:13, 156:17, 173:8, 173:12, 174:15, 176:3, 176:8, 176:24, 179:18, 181:16, 184:7,</p>	<p>184:13, 185:24, 242:9, 242:25, 247:10, 272:25</p> <p>Opioids [1] - 163:12</p> <p>opportunity [9] - 11:15, 36:14, 63:12, 74:11, 77:4, 193:6, 195:16, 202:23, 240:24</p> <p>opposed [2] - 39:22, 116:8</p> <p>opposite [3] - 165:11, 165:13, 258:7</p> <p>orange [1] - 45:7</p> <p>Order [22] - 20:25, 21:1, 21:14, 24:15, 27:23, 30:5, 30:10, 37:18, 39:10, 41:2, 42:15, 58:9, 60:5, 75:12, 146:9, 163:18, 174:24, 206:2, 206:16, 220:15, 259:11, 264:11</p> <p>order [95] - 21:3, 24:18, 25:10, 28:20, 29:3, 29:5, 48:10, 48:11, 48:20, 48:21, 49:4, 53:12, 60:10, 60:24, 60:25, 61:16, 65:6, 70:16, 74:18, 75:9, 75:22, 75:25, 76:2, 76:3, 76:7, 76:15, 76:18, 76:25, 77:1, 77:16, 77:20, 77:23, 78:10, 78:16, 78:17, 79:11, 81:6, 82:23, 83:8, 84:17, 94:11, 95:2, 95:5, 95:6, 95:8, 95:12, 96:3, 96:14, 104:11, 104:22, 105:15, 129:9, 164:2, 164:12, 164:24, 166:18, 203:8, 203:25, 204:13, 204:22, 205:9, 206:13, 206:24, 207:24, 208:3, 208:7, 208:10, 217:13, 217:19, 225:11, 226:22, 227:7, 227:10, 228:1, 229:12, 230:9, 231:10, 231:13, 234:24, 235:25, 244:20, 251:5, 251:10, 251:15, 251:20, 257:23, 260:15,</p>	<p>261:2, 261:21, 267:24, 269:19</p> <p>ordered [2] - 71:1, 232:19</p> <p>ordering [1] - 232:18</p> <p>orders [120] - 24:22, 28:18, 28:19, 42:22, 48:7, 65:5, 70:22, 71:21, 72:25, 73:2, 73:5, 73:9, 77:13, 77:23, 78:11, 78:25, 79:1, 79:2, 79:11, 82:24, 84:16, 89:7, 89:21, 89:23, 91:14, 91:15, 94:8, 96:21, 96:24, 97:21, 98:3, 98:5, 98:18, 100:2, 100:4, 102:15, 102:19, 103:23, 104:8, 104:11, 104:17, 104:23, 105:7, 105:19, 105:22, 105:24, 105:25, 109:3, 112:3, 112:23, 153:11, 153:13, 153:15, 162:17, 165:21, 167:2, 202:8, 203:4, 203:5, 203:6, 204:8, 204:19, 205:13, 205:18, 206:11, 206:12, 206:21, 207:3, 214:8, 214:11, 214:13, 214:16, 215:4, 215:5, 215:9, 215:14, 216:9, 216:12, 216:15, 216:16, 216:20, 218:16, 218:19, 222:21, 227:13, 227:15, 227:21, 227:23, 228:5, 228:12, 228:23, 229:8, 229:15, 230:1, 232:22, 235:7, 236:1, 242:2, 243:6, 245:6, 247:20, 247:24, 248:6, 248:11, 249:6, 251:1, 251:3, 252:2, 253:11, 260:17, 264:20, 265:15, 275:20, 275:24, 276:23</p> <p>Orders [1] - 192:11</p> <p>organization [1] - 41:6</p> <p>organizations [1] - 19:11</p>
--	---	---	--	--

<p>organized [1] - 19:12</p> <p>orient [3] - 56:16, 58:13, 193:13</p> <p>orientation [2] - 34:6, 43:1</p> <p>Oriente [1] - 58:19</p> <p>oriented [1] - 249:11</p> <p>orienting [1] - 57:4</p> <p>original [1] - 42:24</p> <p>originated [1] - 20:3</p> <p>Orleans [1] - 3:8</p> <p>ostensibly [1] - 51:21</p> <p>otherwise [1] - 155:24</p> <p>ought [2] - 51:6, 198:24</p> <p>ourselves [1] - 193:13</p> <p>outline [1] - 13:4</p> <p>outlined [2] - 26:22, 27:1</p> <p>outlining [1] - 27:5</p> <p>outside [17] - 9:13, 11:8, 19:14, 22:7, 84:18, 85:19, 86:16, 117:12, 134:18, 142:4, 145:17, 147:1, 177:6, 186:6, 186:7, 186:9, 223:20</p> <p>over-prescribing [4] - 125:14, 125:17, 125:19, 126:5</p> <p>overall [3] - 59:3, 177:21, 179:11</p> <p>overcome [3] - 178:13, 178:15, 178:17</p> <p>overdose [1] - 181:12</p> <p>Overdoses [1] - 197:15</p> <p>overrule [15] - 26:2, 40:12, 45:24, 53:20, 68:21, 74:13, 77:3, 86:19, 90:10, 91:24, 107:17, 111:13, 154:24, 262:22, 264:2</p> <p>Overruled [2] - 145:9, 165:14</p> <p>overruled [12] - 77:6, 79:6, 106:19, 107:13, 108:20, 109:24, 112:9, 120:2, 187:25, 207:13, 207:19, 239:8</p> <p>oversee [3] - 155:19, 155:24, 156:15</p> <p>oversees [1] - 155:17</p> <p>oversight [1] - 167:8</p> <p>overview [1] - 35:22</p> <p>overwhelming [4] -</p>	<p>120:23, 121:4, 269:10, 269:15</p> <p>own [1] - 90:7</p> <p>owned [1] - 225:10</p> <p>Oxy [1] - 71:14</p> <p>oxy [1] - 71:17</p> <p>oxycodone [47] - 19:1, 19:20, 20:8, 20:10, 23:6, 24:20, 47:3, 47:20, 49:1, 49:10, 49:20, 49:24, 50:1, 54:24, 56:11, 56:24, 58:24, 59:3, 68:5, 70:21, 71:2, 71:4, 71:5, 71:8, 71:10, 71:25, 95:4, 96:18, 96:21, 98:1, 98:4, 98:23, 100:2, 100:14, 100:22, 101:1, 101:3, 101:10, 101:14, 101:18, 106:9, 181:18, 183:2, 219:11, 250:6, 272:24</p> <p>oxycodone-based [1] - 70:21</p> <p>Oxycontin [14] - 18:25, 19:19, 71:8, 138:13, 139:19, 139:25, 140:10, 141:8, 141:23, 141:25, 142:11, 143:11, 143:15, 143:19</p>	<p>140:22, 143:9, 157:13, 157:14, 163:21, 168:5, 168:19, 169:21, 175:4, 176:1, 182:2, 182:21, 183:5, 184:24, 186:21, 188:25, 189:1, 197:24, 198:4, 226:15, 269:8</p> <p>Page [51] - 34:19, 66:15, 120:8, 125:1, 125:10, 125:25, 139:3, 140:6, 142:18, 142:20, 146:21, 147:20, 152:6, 157:11, 163:6, 163:15, 163:17, 163:21, 164:16, 164:19, 166:11, 167:20, 175:10, 175:11, 175:18, 176:1, 176:6, 179:23, 181:2, 181:8, 182:22, 186:19, 192:12, 197:17, 199:11, 199:12, 200:20, 200:22, 224:22, 228:22, 229:14, 256:18, 256:25, 259:25, 260:1, 262:25, 264:5, 267:18, 270:24, 273:3</p> <p>pages [2] - 126:17, 157:12</p> <p>paid [1] - 46:13</p> <p>Pain [1] - 118:22</p> <p>pain [6] - 20:4, 129:20, 129:23, 142:1, 142:13, 199:14</p> <p>pain-killers [1] - 199:14</p> <p>Painkiller [1] - 197:15</p> <p>painkillers [2] - 196:14, 198:12</p> <p>Papantonio [1] - 2:12</p> <p>paper [2] - 24:3, 24:4</p> <p>paragraph [27] - 139:17, 140:9, 140:23, 140:24, 140:25, 141:18, 163:23, 168:5, 169:18, 169:19, 169:20, 170:8, 181:9, 182:24, 198:10, 200:23, 201:4, 202:16, 202:17, 256:19,</p>	<p>259:6, 260:1, 264:7, 264:8, 264:9, 267:19, 269:9</p> <p>Paragraph [2] - 180:2, 202:21</p> <p>paragraphs [2] - 180:1, 257:1</p> <p>pardon [2] - 48:4, 211:14</p> <p>Pardon [1] - 184:3</p> <p>parking [3] - 18:22, 18:23, 19:14</p> <p>part [22] - 15:22, 18:9, 28:14, 67:2, 75:22, 76:9, 83:9, 102:22, 128:23, 133:3, 134:2, 157:6, 171:4, 180:13, 201:4, 226:11, 254:5, 254:15, 262:1, 263:1, 270:10</p> <p>partial [1] - 188:7</p> <p>participants [3] - 185:22, 185:23, 186:4</p> <p>participate [4] - 17:13, 18:3, 18:4, 259:4</p> <p>participated [2] - 18:13, 19:22</p> <p>participating [1] - 195:17</p> <p>participation [2] - 15:8, 37:21</p> <p>particular [15] - 17:20, 26:13, 63:20, 64:7, 64:16, 67:4, 70:20, 71:13, 71:16, 82:15, 89:13, 188:20, 188:21, 244:6, 256:21</p> <p>particularly [1] - 233:19</p> <p>parties [1] - 63:19</p> <p>parts [2] - 40:1, 171:5</p> <p>pass [1] - 12:23</p> <p>passed [1] - 187:6</p> <p>passing [1] - 191:3</p> <p>past [7] - 88:17, 90:19, 170:10, 228:10, 248:20, 250:1, 250:5</p> <p>patient [8] - 116:22, 149:3, 149:4, 149:11, 149:16, 193:20, 196:7, 196:9</p> <p>patients [13] - 18:21, 18:24, 19:2, 121:23, 148:25, 193:20, 195:3, 195:6, 195:9, 196:4, 217:7, 218:3, 218:7</p>	<p>patrol [1] - 11:12</p> <p>pattern [12] - 60:1, 60:8, 82:25, 203:6, 204:9, 204:13, 204:19, 205:10, 231:18, 232:10, 232:25, 233:3</p> <p>patterns [4] - 23:4, 49:25, 55:1, 58:6</p> <p>Patterson [2] - 121:21, 122:4</p> <p>PAUL [2] - 2:3, 5:9</p> <p>Pause [3] - 113:10, 174:11, 190:23</p> <p>pause [2] - 72:12, 246:20</p> <p>PDF [1] - 139:4</p> <p>PEARL [1] - 3:6</p> <p>peer [1] - 223:14</p> <p>peer-reviewed [1] - 223:14</p> <p>pending [5] - 31:2, 34:9, 151:9, 151:11, 151:12</p> <p>peninsula [2] - 17:23, 17:24</p> <p>Pensacola [1] - 2:14</p> <p>people [23] - 16:2, 16:15, 17:10, 20:5, 23:17, 129:23, 159:11, 183:14, 183:20, 183:22, 184:7, 184:9, 184:11, 184:14, 184:17, 186:14, 186:17, 187:6, 196:13, 198:11, 199:13, 263:23, 266:7</p> <p>per [6] - 94:5, 94:6, 94:7, 175:23, 176:3</p> <p>percent [74] - 96:22, 96:25, 97:2, 97:3, 97:5, 97:6, 98:4, 98:6, 98:8, 98:9, 98:10, 98:11, 98:17, 98:19, 98:20, 98:21, 98:23, 98:24, 100:3, 100:5, 100:6, 100:12, 100:14, 100:15, 100:23, 100:24, 100:25, 101:2, 101:4, 101:6, 101:11, 101:13, 101:15, 101:16, 101:19, 101:21, 121:14, 121:22, 122:6, 122:11, 122:15, 135:18, 152:23, 152:24,</p>
--	--	---	---	---

<p>153:5, 153:8, 153:9, 157:19, 181:19, 183:2, 205:23, 205:24, 208:17, 210:1, 210:2, 210:4, 216:19, 216:20, 217:3, 217:15, 219:13, 219:16, 219:20, 219:21, 220:8, 226:20, 228:24, 250:7, 250:20, 273:16, 276:6 percentage [1] - 153:22 Percocet [1] - 19:20 perfect [1] - 123:13 perfectly [1] - 123:3 performed [13] - 69:4, 97:9, 115:5, 208:14, 208:19, 208:21, 209:8, 209:10, 209:12, 209:14, 209:16, 210:13, 216:6 performing [5] - 26:23, 34:16, 36:10, 42:8, 74:18 perhaps [3] - 14:7, 31:23, 69:14 period [25] - 45:17, 55:8, 58:11, 62:6, 63:1, 63:2, 93:2, 127:19, 130:8, 134:12, 158:12, 158:15, 182:13, 201:22, 206:3, 207:5, 230:15, 232:11, 244:9, 251:16, 259:1, 269:17, 274:12, 275:25, 276:19 periods [2] - 85:17, 271:8 permissible [2] - 53:20, 136:10 permit [1] - 178:1 permitted [3] - 14:22, 30:13, 82:8 person [2] - 54:12, 225:6 personal [3] - 78:21, 185:18, 260:8 personally [1] - 53:16 personnel [1] - 258:15 PETER [1] - 2:12 Pharmaceutical [7] - 22:7, 22:11, 22:21, 24:22, 40:24, 85:5, 260:13</p>	<p>pharmaceutical [3] - 153:1, 180:12, 267:22 Pharmacies [2] - 131:11, 193:18 pharmacies [60] - 9:11, 17:5, 23:6, 39:7, 68:9, 69:5, 70:12, 92:22, 92:23, 103:4, 116:9, 129:19, 130:2, 131:11, 131:14, 131:15, 131:25, 132:20, 134:11, 134:16, 134:17, 134:21, 134:25, 135:8, 135:20, 136:3, 136:4, 136:16, 136:21, 137:8, 137:13, 137:18, 148:14, 149:19, 150:14, 153:15, 155:23, 156:12, 157:22, 158:14, 158:18, 169:23, 171:7, 176:24, 185:13, 186:24, 194:17, 206:17, 209:18, 215:9, 216:7, 224:6, 232:6, 271:15, 271:20, 271:21, 271:22, 272:8, 272:18, 273:13 pharmacist [9] - 132:3, 132:4, 132:7, 132:25, 133:1, 159:19, 160:6, 160:7, 160:10 pharmacists' [1] - 150:6 pharmacists [8] - 132:23, 133:6, 133:8, 133:16, 135:4, 160:19, 168:20, 169:4 pharmacists' [1] - 216:11 pharmacy [67] - 9:18, 19:18, 48:8, 48:10, 59:11, 60:24, 62:5, 65:6, 68:13, 69:10, 72:23, 73:10, 75:9, 129:19, 130:2, 130:13, 130:21, 131:22, 132:5, 133:17, 133:21, 134:7, 135:1, 135:11, 135:14, 135:17, 135:25,</p>	<p>137:19, 148:23, 149:1, 149:21, 149:25, 150:1, 150:5, 150:9, 151:17, 151:20, 158:6, 159:13, 159:23, 161:5, 161:6, 161:11, 161:12, 161:22, 161:23, 162:2, 162:13, 170:2, 171:25, 173:9, 177:1, 177:2, 204:17, 205:1, 205:2, 205:3, 215:13, 227:12, 230:14, 239:25, 241:2, 272:5, 272:8 Pharmacy [15] - 39:5, 39:7, 40:19, 55:5, 55:14, 57:2, 131:15, 151:17, 151:23, 152:14, 152:15, 152:17, 152:20, 153:4 pharmacy's [2] - 150:6, 205:3 Philadelphia [2] - 6:6, 6:13 phone [1] - 160:3 phonetic [1] - 37:22 phrase [2] - 204:5, 204:6 physician [2] - 19:13, 116:18 physicians [10] - 120:15, 120:18, 120:23, 121:4, 122:9, 122:20, 141:24, 142:12, 168:19, 169:3 pick [3] - 199:8, 245:18, 270:22 picked [1] - 11:17 pickers [4] - 94:24, 95:6, 95:14, 101:7 picking [2] - 95:5, 276:6 picture [1] - 215:19 PIFKO [1] - 3:16 pill [16] - 18:20, 18:21, 19:9, 20:4, 48:7, 71:10, 128:16, 130:10, 130:19, 156:23, 157:1, 157:17, 157:22, 157:25, 158:2, 167:23 pillars [1] - 55:25 pills [39] - 17:1, 21:7,</p>	<p>21:9, 21:12, 24:20, 24:22, 46:5, 60:24, 61:1, 61:2, 61:4, 61:5, 61:6, 79:22, 80:14, 80:17, 80:21, 80:23, 87:22, 92:15, 92:16, 95:14, 97:16, 130:9, 130:17, 131:6, 134:7, 149:22, 208:7, 217:3, 217:12, 230:17, 231:21, 231:22, 231:24, 232:18, 233:12, 234:21 pinkish [1] - 56:21 place [9] - 60:5, 62:20, 72:6, 80:4, 198:25, 203:11, 233:25, 258:12, 275:13 placed [4] - 35:25, 78:11, 88:16, 89:18 places [4] - 48:10, 97:21, 193:10, 244:12 Plaintiff [5] - 1:5, 1:11, 2:2, 3:2, 4:1 plaintiff [6] - 116:1, 116:4, 155:13, 186:10, 189:10, 223:22 Plaintiffs [2] - 10:3, 278:22 plaintiffs [3] - 7:16, 154:12, 254:18 PLAINTIFFS' [1] - 10:9 plaintiffs' [8] - 145:8, 154:16, 155:7, 182:5, 196:23, 210:20, 222:19, 254:19 planned [1] - 12:21 play [1] - 148:17 played [3] - 164:22, 185:12, 235:12 plays [1] - 185:8 Pleasant [3] - 3:15, 4:4, 4:9 pled [1] - 19:6 plug [1] - 113:15 Plus [7] - 151:17, 151:23, 152:13, 152:15, 152:17, 152:20, 153:3 podium [1] - 8:22 point [52] - 13:18, 22:10, 26:3, 29:17, 31:15, 34:14, 35:10, 42:2, 43:18, 44:1,</p>	<p>46:5, 52:11, 52:19, 52:24, 53:6, 55:3, 64:7, 65:21, 68:17, 76:25, 91:25, 93:12, 113:11, 121:14, 154:14, 154:19, 158:10, 158:17, 161:5, 169:17, 183:24, 190:1, 198:21, 198:25, 199:1, 206:12, 206:21, 212:8, 217:3, 218:22, 227:2, 236:4, 236:9, 236:12, 237:21, 241:6, 242:1, 244:18, 251:4, 265:9, 269:18 pointed [2] - 116:8, 174:4 points [3] - 52:10, 190:7, 237:14 pole [1] - 263:19 Police [1] - 11:6 police [2] - 11:18, 12:22 policies [17] - 9:17, 27:17, 27:20, 42:14, 50:6, 54:6, 54:16, 59:25, 60:6, 60:9, 61:25, 62:22, 77:11, 77:22, 78:2, 78:3, 78:6 policing [1] - 12:13 policy [35] - 9:12, 9:16, 27:16, 54:6, 54:8, 54:13, 56:20, 57:25, 58:17, 65:4, 118:3, 118:8, 119:4, 119:9, 119:18, 120:22, 158:4, 159:10, 161:9, 162:1, 162:4, 252:19, 253:15, 257:5, 257:17, 258:4, 258:10, 258:12, 258:17, 260:19, 273:23, 274:1, 274:14, 274:17, 275:13 Policy [2] - 118:25, 197:14 Ponc [1] - 2:4 Ponce [1] - 2:16 population [3] - 19:2, 175:24, 241:17 portion [3] - 13:16, 82:12, 267:16 portions [1] - 16:12 posed [1] - 25:1</p>
--	--	---	--	--

<p>position [5] - 9:2, 9:15, 12:16, 178:22, 233:18</p> <p>positive [2] - 173:18, 273:11</p> <p>Possibility [1] - 154:1</p> <p>possibility [8] - 135:17, 158:3, 205:11, 212:18, 219:1, 228:16, 240:14, 240:17</p> <p>possible [3] - 83:23, 94:18, 228:7</p> <p>possibly [1] - 156:24</p> <p>post [3] - 25:10, 61:6, 103:16</p> <p>post-distribution [1] - 61:6</p> <p>post-shipment [1] - 103:16</p> <p>posting [1] - 15:19</p> <p>potential [12] - 32:1, 76:15, 79:24, 104:3, 170:9, 177:21, 195:3, 195:21, 205:6, 217:12, 217:18, 243:10</p> <p>potentially [1] - 243:6</p> <p>Powell [1] - 2:6</p> <p>powers [1] - 16:7</p> <p>PR [2] - 2:5, 2:17</p> <p>practical [1] - 15:15</p> <p>practice [4] - 65:5, 159:1, 259:11, 259:17</p> <p>practitioner [2] - 17:6, 117:2</p> <p>practitioners [2] - 17:5, 170:20</p> <p>Pre [1] - 168:2</p> <p>pre [18] - 39:16, 39:23, 45:22, 103:12, 103:13, 103:14, 103:15, 168:7, 168:21, 169:5, 169:11, 169:14, 169:24, 170:4, 269:2</p> <p>pre-2007 [6] - 60:10, 63:2, 63:8, 66:12, 73:14, 206:11</p> <p>pre-2008 [1] - 61:3</p> <p>pre-dates [2] - 45:22, 269:2</p> <p>Pre-registration [1] - 168:2</p> <p>pre-registration [7] - 168:7, 168:21, 169:5, 169:11, 169:14, 169:24, 170:4</p>	<p>pre-shipment [6] - 103:12, 103:13, 103:14, 103:15</p> <p>pre-shipping [1] - 103:12</p> <p>pre-trial [2] - 39:16, 39:23</p> <p>precedence [1] - 162:10</p> <p>precedent [1] - 34:10</p> <p>precise [1] - 235:23</p> <p>precisely [3] - 220:14, 241:2, 241:4</p> <p>predating [1] - 269:6</p> <p>preliminary [1] - 44:9</p> <p>prepare [4] - 27:1, 44:18, 47:8, 50:15</p> <p>prepared [11] - 27:11, 33:23, 35:16, 35:22, 51:2, 51:4, 51:10, 60:12, 74:21, 82:1, 223:19</p> <p>preparing [1] - 51:8</p> <p>prescribe [8] - 120:16, 120:23, 121:5, 121:15, 141:25, 242:8, 242:24, 256:21</p> <p>prescribed [4] - 196:8, 196:14, 198:12, 199:14</p> <p>prescriber [2] - 131:9, 133:18</p> <p>prescribers [6] - 116:15, 117:9, 117:14, 126:5, 155:23, 156:8</p> <p>prescribing [19] - 117:1, 117:2, 117:20, 125:14, 125:17, 125:19, 126:5, 127:24, 128:13, 129:11, 130:1, 243:25, 244:3, 244:8, 244:16, 247:21, 248:4, 248:5</p> <p>prescription [61] - 56:9, 107:5, 107:23, 108:5, 108:16, 110:8, 110:25, 111:20, 119:5, 129:5, 129:10, 130:11, 130:18, 130:21, 131:8, 131:9, 131:12, 132:8, 132:11, 132:13, 132:21, 132:24, 133:17, 133:18, 133:21,</p>	<p>133:22, 134:1, 134:5, 134:12, 136:13, 137:23, 137:25, 138:8, 144:4, 144:8, 144:16, 148:19, 149:12, 154:5, 156:13, 159:19, 160:7, 176:2, 176:8, 176:24, 184:13, 185:23, 193:5, 193:25, 194:2, 194:6, 196:13, 198:11, 198:19, 199:14, 242:9, 242:14, 242:15, 242:25, 247:10, 272:25</p> <p>Prescription [2] - 138:13, 197:14</p> <p>prescriptions [27] - 19:15, 19:16, 19:18, 48:3, 48:5, 116:17, 116:20, 119:8, 127:18, 129:14, 129:20, 130:1, 130:2, 130:5, 130:7, 131:12, 132:2, 134:8, 148:22, 148:25, 149:4, 156:9, 160:20, 218:11, 242:4, 242:18, 245:5</p> <p>present [12] - 13:9, 19:10, 30:13, 53:1, 90:15, 133:1, 182:8, 185:13, 217:20, 222:6, 239:11, 239:19</p> <p>presentation [6] - 43:20, 50:18, 174:18, 175:3, 224:21, 224:22</p> <p>presentations [1] - 277:5</p> <p>presented [3] - 13:15, 224:12, 263:8</p> <p>presenting [3] - 29:14, 146:25, 149:11</p> <p>preserved [1] - 86:20</p> <p>press [1] - 74:14</p> <p>pretty [7] - 15:14, 24:2, 55:2, 94:16, 170:22, 208:14, 219:18</p> <p>prevalence [1] - 141:8</p> <p>prevent [21] - 24:13, 28:25, 30:1, 30:11, 76:5, 107:4, 107:9, 107:22, 108:4,</p>	<p>108:16, 110:7, 146:7, 149:6, 151:15, 177:24, 191:12, 233:8, 251:19, 269:11, 269:17, 270:4</p> <p>preventing [1] - 185:8</p> <p>prevention [1] - 23:21</p> <p>prevents [3] - 177:22, 208:8, 208:9</p> <p>previous [11] - 36:23, 62:15, 75:8, 88:1, 91:6, 93:16, 171:2, 171:22, 198:17, 215:18</p> <p>previously [5] - 103:3, 168:13, 240:5, 249:8, 249:16</p> <p>primarily [4] - 19:17, 55:16, 61:20, 64:22</p> <p>primary [2] - 102:23, 141:25</p> <p>Privacy [1] - 149:6</p> <p>privacy [1] - 149:8</p> <p>privy [1] - 83:6</p> <p>problem [7] - 113:14, 125:11, 125:17, 126:15, 178:11, 183:18, 235:5</p> <p>Problem [1] - 138:14</p> <p>problematic [1] - 158:13</p> <p>problems [3] - 122:21, 126:7, 177:21</p> <p>procedural [6] - 25:4, 25:8, 25:15, 56:20, 154:17, 154:18</p> <p>procedure [6] - 9:12, 9:16, 54:9, 54:13, 58:17, 274:16</p> <p>procedures [15] - 24:17, 24:18, 27:16, 27:17, 27:20, 27:24, 42:14, 50:6, 54:16, 59:25, 60:9, 62:1, 62:22, 77:11, 77:22</p> <p>proceed [5] - 33:3, 59:20, 112:19, 113:24, 115:10</p> <p>proceeding [2] - 31:23, 157:9</p> <p>Proceedings [2] - 6:19, 113:20</p> <p>proceedings [1] - 278:21</p> <p>PROCEEDINGS [1] - 7:1</p> <p>process [12] - 9:1, 9:4, 73:25, 74:1, 76:1, 76:9, 77:20, 77:24,</p>	<p>79:15, 155:25, 169:24, 170:4</p> <p>Proctor [1] - 2:12</p> <p>produce [2] - 96:7, 181:15</p> <p>produced [3] - 6:19, 102:11, 248:19</p> <p>product [4] - 16:24, 71:3, 178:9, 184:5</p> <p>production [3] - 180:4, 181:18, 273:10</p> <p>products [6] - 39:9, 67:8, 68:5, 71:2, 144:22, 259:12</p> <p>professional [2] - 10:22, 133:23</p> <p>professionals [2] - 115:1, 134:9</p> <p>proffer [1] - 25:22</p> <p>Program [2] - 146:9, 274:9</p> <p>program [6] - 67:23, 124:8, 166:13, 235:3, 275:7, 276:15</p> <p>programs [2] - 124:3, 251:2</p> <p>prohibit [1] - 149:7</p> <p>prohibits [1] - 159:11</p> <p>project [1] - 124:12</p> <p>promote [1] - 141:23</p> <p>promoted [2] - 12:15, 140:10</p> <p>promoting [1] - 142:11</p> <p>promotion [2] - 12:10, 141:4</p> <p>promotional [1] - 141:24</p> <p>prompted [2] - 258:4, 258:10</p> <p>proof [1] - 265:3</p> <p>proper [11] - 13:14, 35:2, 43:17, 51:14, 65:15, 117:1, 132:10, 147:14, 154:22, 171:1, 235:6</p> <p>properly [5] - 39:22, 104:6, 133:19, 133:23, 157:23</p> <p>proposal [1] - 119:7</p> <p>proposed [5] - 203:14, 203:16, 203:20, 205:15, 249:5</p> <p>proposition [1] - 138:12</p> <p>propositions [1] - 161:1</p> <p>proprietary [1] - 178:4</p> <p>protocols [1] - 148:6</p>
--	--	---	--	---

<p>provide [13] - 13:5, 24:5, 114:5, 145:12, 167:4, 188:19, 195:9, 196:4, 199:12, 210:21, 220:19, 240:23, 247:18</p> <p>provided [15] - 13:8, 37:23, 44:10, 44:19, 57:15, 63:24, 83:9, 95:24, 145:22, 146:19, 148:9, 220:18, 253:16, 255:3, 271:11</p> <p>providers [1] - 195:17</p> <p>provides [2] - 51:14, 95:1</p> <p>providing [1] - 177:12</p> <p>provisions [2] - 133:25, 203:22</p> <p>prudent [2] - 182:15, 272:6</p> <p>public [13] - 25:2, 119:16, 119:24, 162:9, 162:10, 162:11, 162:16, 222:23, 224:16, 224:17, 251:9, 251:21, 261:14</p> <p>publication [8] - 126:13, 127:6, 142:4, 173:24, 197:6, 199:9, 248:22, 273:10</p> <p>publications [2] - 196:24, 224:15</p> <p>publicly [1] - 121:13</p> <p>publish [8] - 13:9, 27:8, 47:14, 50:22, 60:16, 75:1, 82:9, 223:14</p> <p>published [13] - 34:5, 37:5, 38:17, 39:11, 39:13, 41:8, 44:25, 47:15, 50:23, 51:4, 250:14, 255:13, 266:6</p> <p>publishing [4] - 44:21, 65:8, 158:8, 274:3</p> <p>pull [2] - 66:20, 113:15</p> <p>pulls [1] - 150:5</p> <p>purchase [17] - 17:4, 61:1, 61:7, 61:23, 61:24, 63:20, 64:11, 70:5, 70:6, 73:11, 73:14, 75:10, 75:18, 84:1, 84:5, 148:15</p> <p>purchases [2] - 70:17, 176:23</p> <p>purchasing [2] - 67:7,</p>	<p>83:5</p> <p>Purdue [7] - 140:9, 140:10, 140:12, 140:16, 141:20, 141:22, 143:13</p> <p>Purdue's [1] - 142:10</p> <p>pure [3] - 89:25, 90:6, 250:13</p> <p>purport [1] - 220:10</p> <p>purported [1] - 32:16</p> <p>purports [2] - 63:1, 271:8</p> <p>purpose [10] - 14:19, 25:15, 28:1, 29:18, 84:12, 84:15, 147:2, 239:20, 243:7, 247:17</p> <p>purposes [16] - 16:13, 17:17, 32:13, 34:6, 42:3, 42:25, 49:4, 96:5, 105:14, 120:24, 121:15, 139:23, 152:7, 176:20, 200:20</p> <p>pursuant [3] - 9:7, 48:24, 242:14</p> <p>push [1] - 29:11</p> <p>put [29] - 12:25, 21:12, 33:14, 45:20, 64:6, 66:20, 95:14, 120:5, 135:12, 138:24, 162:23, 163:8, 174:23, 186:20, 197:11, 198:3, 200:18, 202:13, 219:2, 220:8, 230:21, 238:10, 251:22, 252:8, 256:15, 267:10, 270:23, 274:1, 275:13</p> <p>putting [1] - 93:23</p>	<p>questioning [2] - 112:12, 112:17</p> <p>questions [24] - 39:21, 44:10, 65:25, 74:12, 113:23, 114:2, 115:7, 115:18, 115:20, 115:23, 128:5, 155:16, 160:6, 160:8, 160:17, 172:11, 188:2, 199:21, 226:12, 235:18, 261:8, 264:2, 265:20, 273:3</p> <p>quick [4] - 8:4, 22:9, 95:9, 215:16</p> <p>quickly [5] - 7:13, 19:2, 86:25, 142:23, 246:6</p> <p>quiet [1] - 52:7</p> <p>quit [1] - 113:13</p> <p>quite [1] - 85:23</p> <p>quota [29] - 144:9, 180:4, 180:5, 180:8, 180:16, 180:20, 180:24, 181:5, 181:7, 181:18, 182:3, 182:7, 182:12, 183:12, 183:14, 183:17, 183:18, 184:2, 184:4, 200:9, 245:11, 245:14, 245:20, 246:6, 247:16, 247:22, 248:3, 249:2, 249:15</p> <p>quotas [1] - 179:18</p> <p>quote [2] - 199:13, 199:15</p> <p>Quote [1] - 180:9</p> <p>quoted [2] - 187:2, 202:14</p>	<p>96:10, 97:7, 101:22, 103:3, 104:20, 107:3, 113:21, 114:2, 115:14, 127:9, 147:2, 190:13, 199:8, 200:19, 212:24, 235:23, 239:22, 243:15, 264:10, 265:23, 267:21</p> <p>RAFALSKI [1] - 10:9</p> <p>Rafalski's [4] - 30:18, 146:21, 147:6, 186:18</p> <p>Rafferty [1] - 2:12</p> <p>raging [1] - 182:14</p> <p>raise [3] - 10:8, 94:14, 244:20</p> <p>raises [1] - 245:11</p> <p>raising [2] - 94:13, 182:15</p> <p>ran [3] - 12:16, 227:5</p> <p>range [4] - 83:25, 142:12, 185:11, 220:8</p> <p>ranges [1] - 185:15</p> <p>ranks [1] - 11:13</p> <p>Rannazzisi [12] - 37:7, 41:11, 121:11, 123:6, 123:8, 123:14, 252:23, 266:9, 268:16, 268:25, 269:9, 269:15</p> <p>Rannazzisi's [1] - 39:2</p> <p>rarely [2] - 168:20, 169:4</p> <p>rate [1] - 181:12</p> <p>rather [3] - 9:20, 19:2, 63:11</p> <p>raw [2] - 16:22, 16:24</p> <p>re [6] - 74:7, 110:2, 156:8, 156:12, 224:6, 249:11</p> <p>re-ask [1] - 110:2</p> <p>re-oriented [1] - 249:11</p> <p>re-registering [1] - 156:12</p> <p>re-registration [2] - 156:8, 224:6</p> <p>re-state [1] - 74:7</p> <p>read [28] - 49:4, 49:18, 98:25, 99:13, 99:15, 99:25, 101:23, 103:10, 125:25, 138:25, 143:25, 163:2, 163:4, 164:9, 174:13, 187:9, 189:6, 199:11,</p>	<p>229:3, 250:3, 255:16, 261:19, 261:22, 262:13, 268:4, 268:7, 269:12, 269:13</p> <p>reading [5] - 13:24, 39:17, 96:20, 187:22, 200:25</p> <p>ready [2] - 7:6, 75:6</p> <p>real [10] - 22:9, 95:9, 197:1, 220:11, 220:16, 220:23, 222:2, 223:3, 235:3, 244:3</p> <p>Real [1] - 8:4</p> <p>realize [3] - 21:5, 43:15, 131:3</p> <p>realizing [1] - 184:6</p> <p>really [1] - 124:6</p> <p>realtime [1] - 72:8</p> <p>Reardon [1] - 58:3</p> <p>reason [20] - 122:16, 126:10, 147:3, 155:5, 155:12, 172:5, 173:3, 181:25, 185:20, 186:2, 213:3, 226:11, 226:25, 231:4, 241:15, 243:1, 243:12, 260:17, 260:18, 264:1</p> <p>reasonable [2] - 113:4, 156:5</p> <p>reasonably [1] - 115:4</p> <p>reasons [4] - 94:17, 219:7, 225:7, 244:17</p> <p>recalculates [1] - 93:11</p> <p>recalled [1] - 220:21</p> <p>receive [4] - 166:15, 166:22, 167:12, 183:15</p> <p>received [2] - 15:10, 202:4</p> <p>receiving [4] - 55:15, 65:5, 134:17, 218:7</p> <p>recent [1] - 248:21</p> <p>Recess [3] - 43:11, 113:19, 199:4</p> <p>recess [1] - 199:2</p> <p>recessed [1] - 278:15</p> <p>recite [1] - 215:15</p> <p>recognize [13] - 33:7, 116:15, 142:2, 142:6, 146:2, 147:24, 152:11, 191:22, 203:7, 207:9, 214:7, 256:8, 256:11</p>
Q		R		
<p>qualifications [5] - 14:19, 14:25, 25:18, 31:3, 33:3</p> <p>qualified [4] - 30:9, 32:15, 33:7, 111:8</p> <p>qualifies [1] - 204:10</p> <p>qualify [1] - 43:24</p> <p>Quantico [1] - 15:13</p> <p>quantity [2] - 48:20, 71:13</p> <p>quarter [1] - 238:3</p> <p>quarterly [2] - 61:14, 73:5</p> <p>questioned [1] - 253:14</p>		<p>R-a-f-a-l-s-k-i [1] - 10:7</p> <p>Rafalski [58] - 10:4, 10:7, 10:14, 10:19, 10:20, 10:23, 13:2, 14:24, 15:24, 22:9, 30:9, 32:1, 33:1, 33:19, 34:14, 36:22, 44:6, 46:3, 46:13, 49:25, 52:1, 54:1, 58:25, 59:18, 60:20, 61:10, 62:9, 63:19, 64:10, 74:16, 75:2, 75:25, 77:8, 81:20, 82:15, 86:9, 92:18,</p>		

<p>recognizes [2] - 120:22, 269:9</p> <p>recollection [12] - 124:18, 143:22, 144:3, 146:16, 146:25, 150:17, 196:17, 210:5, 213:19, 221:9, 264:25, 275:18</p> <p>recommendation [1] - 24:21</p> <p>recommendations [1] - 38:10</p> <p>recommending [1] - 245:23</p> <p>reconsideration [1] - 44:2</p> <p>record [41] - 10:6, 10:18, 14:10, 14:21, 19:6, 34:12, 34:22, 39:17, 45:21, 49:5, 49:19, 59:2, 63:23, 63:24, 66:11, 78:20, 79:3, 84:24, 86:5, 86:16, 86:21, 91:21, 98:25, 99:2, 99:25, 101:23, 102:14, 103:10, 104:17, 105:14, 106:3, 112:16, 126:24, 126:25, 147:7, 187:19, 199:12, 229:20, 235:20, 269:21, 278:21</p> <p>recorded [1] - 6:19</p> <p>Recording [1] - 235:12</p> <p>recordkeeping [4] - 201:24, 203:22, 270:8, 275:18</p> <p>records [12] - 20:18, 29:22, 42:13, 119:24, 129:18, 135:1, 135:2, 254:16, 270:5, 270:12, 272:10</p> <p>recovering [1] - 218:3</p> <p>recreate [2] - 223:11, 244:6</p> <p>recurs [1] - 51:18</p> <p>red [10] - 34:8, 34:11, 56:21, 56:23, 91:16, 132:12, 275:6, 275:10, 275:12, 275:14</p> <p>reduced [2] - 183:1, 183:12</p> <p>Reed [2] - 6:4, 6:11</p> <p>refer [4] - 23:18, 139:8, 180:4, 226:16</p>	<p>reference [14] - 51:5, 132:17, 139:5, 142:7, 203:24, 225:16, 234:8, 234:15, 252:22, 252:23, 258:22, 259:7, 263:2, 264:6</p> <p>referenced [3] - 22:12, 34:7, 34:8</p> <p>referencing [5] - 44:11, 119:6, 145:7, 263:22, 264:15</p> <p>referred [5] - 42:20, 94:23, 133:6, 171:3, 195:13</p> <p>referring [2] - 171:21, 258:3</p> <p>refers [1] - 204:8</p> <p>refine [1] - 239:5</p> <p>reflect [2] - 63:8, 73:24</p> <p>reflected [1] - 275:16</p> <p>reflection [1] - 9:15</p> <p>reflects [2] - 63:3, 220:4</p> <p>refresh [3] - 146:24, 152:4, 252:7</p> <p>refreshing [1] - 221:9</p> <p>refused [1] - 177:4</p> <p>refusing [1] - 158:5</p> <p>regard [6] - 60:2, 106:2, 145:12, 156:20, 171:16, 178:20</p> <p>Regarding [1] - 152:13</p> <p>regarding [21] - 30:18, 32:4, 44:19, 47:18, 58:7, 78:11, 96:18, 97:25, 124:17, 126:5, 136:13, 141:3, 152:13, 182:7, 196:22, 203:22, 206:17, 209:18, 238:5, 238:14, 241:7</p> <p>regards [7] - 29:23, 38:8, 158:8, 226:1, 257:11, 257:17, 275:13</p> <p>region [4] - 59:11, 92:19, 176:3, 176:4</p> <p>Register [8] - 39:11, 40:20, 120:21, 248:22, 249:4, 250:15, 266:6, 269:24</p> <p>register [1] - 171:7</p> <p>registered [4] - 156:21, 157:18,</p>	<p>269:10, 269:15</p> <p>registering [2] - 156:12</p> <p>registers [1] - 131:14</p> <p>registrant [15] - 17:12, 28:25, 82:22, 84:10, 148:15, 159:17, 159:21, 170:9, 170:25, 171:20, 200:3, 201:2, 233:9, 245:24, 246:2</p> <p>registrant's [1] - 261:14</p> <p>registrants [17] - 16:14, 16:18, 16:21, 17:4, 30:4, 81:22, 83:25, 155:19, 156:16, 160:4, 168:8, 168:18, 169:3, 169:12, 186:6, 194:23, 261:11</p> <p>registration [28] - 25:1, 131:18, 150:6, 150:7, 151:10, 155:24, 155:25, 156:7, 156:8, 157:1, 167:22, 168:2, 168:7, 168:13, 168:21, 169:5, 169:11, 169:14, 169:24, 170:4, 170:21, 171:17, 172:2, 172:6, 172:13, 173:4, 224:5, 224:6</p> <p>Registration [1] - 15:23</p> <p>registrations [4] - 16:15, 143:5, 156:22, 157:25</p> <p>regular [2] - 158:21, 159:1</p> <p>regulate [2] - 16:12, 143:2</p> <p>regulation [23] - 61:18, 82:22, 82:23, 84:9, 132:15, 132:16, 132:18, 142:24, 202:11, 202:14, 203:9, 203:10, 203:14, 203:17, 203:21, 257:18, 260:15, 261:2, 261:21, 264:24, 265:3, 265:8, 265:16</p> <p>regulations [9] - 30:4, 116:25, 117:19, 156:1, 255:7, 255:9,</p>	<p>256:20, 257:6, 270:7</p> <p>Regulations [1] - 37:6</p> <p>regulator [1] - 236:7</p> <p>regulators [1] - 236:14</p> <p>Regulatory [1] - 163:11</p> <p>regulatory [3] - 168:7, 185:1, 203:7</p> <p>relate [1] - 7:20</p> <p>related [4] - 45:21, 54:16, 62:1, 165:8</p> <p>relates [1] - 13:15</p> <p>relating [4] - 119:5, 132:24, 175:8, 194:21</p> <p>relation [1] - 153:17</p> <p>relationship [5] - 106:2, 116:21, 132:10, 149:18, 260:8</p> <p>relationships [1] - 232:7</p> <p>relative [1] - 129:6</p> <p>relayed [1] - 210:19</p> <p>relevance [1] - 25:14</p> <p>relevant [4] - 154:21, 154:24, 190:9, 256:14</p> <p>reliable [2] - 114:23, 202:5</p> <p>reliance [7] - 14:20, 35:17, 36:19, 42:5, 42:10, 102:7, 138:17</p> <p>relied [16] - 14:20, 33:20, 33:24, 34:15, 35:23, 37:14, 38:11, 38:17, 39:19, 41:7, 41:17, 41:24, 138:11, 138:15, 211:3, 220:22</p> <p>rely [15] - 51:15, 52:20, 53:14, 79:10, 114:18, 114:25, 115:4, 127:1, 156:3, 156:11, 162:16, 167:22, 180:23, 268:9</p> <p>remand [1] - 154:13</p> <p>remanded [1] - 147:4</p> <p>remember [22] - 13:20, 159:25, 160:12, 167:24, 173:22, 178:24, 190:25, 196:15, 208:15, 208:16, 209:22, 217:4, 221:12, 230:13, 230:17, 243:18, 245:13, 252:21, 252:22, 253:19,</p>	<p>273:24, 277:12</p> <p>remind [2] - 56:25, 268:12</p> <p>reminder [1] - 58:20</p> <p>remove [4] - 137:5, 150:8, 238:1, 238:3</p> <p>removed [1] - 104:11</p> <p>removing [2] - 220:6, 225:23</p> <p>renew [1] - 30:22</p> <p>renewals [2] - 15:23, 158:2</p> <p>Reno [4] - 38:6, 38:12, 38:16</p> <p>repeat [5] - 33:2, 85:8, 111:18, 155:2, 231:17</p> <p>repeatedly [2] - 86:7, 159:18</p> <p>rephrase [3] - 110:15, 189:13, 227:17</p> <p>replicate [3] - 83:12, 87:2, 230:24</p> <p>replicated [1] - 232:9</p> <p>report [101] - 26:8, 26:9, 26:21, 29:11, 30:6, 32:16, 38:6, 38:12, 38:16, 42:4, 51:8, 61:4, 61:7, 61:23, 63:20, 64:14, 64:16, 64:21, 66:7, 67:2, 67:10, 67:12, 67:15, 72:4, 73:11, 73:13, 73:14, 75:21, 85:19, 85:21, 85:24, 86:4, 86:17, 99:25, 100:20, 101:8, 109:2, 128:11, 130:24, 130:25, 133:4, 135:12, 139:23, 140:15, 141:13, 141:14, 143:8, 143:13, 145:12, 146:21, 148:9, 154:20, 154:24, 165:21, 166:10, 166:11, 170:16, 172:18, 179:20, 182:7, 188:15, 191:22, 192:9, 199:24, 200:18, 202:7, 210:17, 211:12, 211:15, 211:18, 211:20, 213:6, 214:23, 215:2, 216:3, 216:6, 217:10, 222:7, 224:15, 230:12, 230:14, 230:20,</p>
---	--	--	---	---

<p>250:3, 258:6, 258:12, 260:17, 261:7, 261:8, 261:12, 262:7, 262:9, 262:11, 264:20, 265:15, 266:17, 268:10, 272:22</p> <p>Report [2] - 138:13, 264:11</p> <p>report-only [1] - 258:12</p> <p>reportable [1] - 230:4</p> <p>reported [27] - 25:5, 28:18, 40:24, 42:23, 61:11, 72:3, 73:6, 73:16, 76:16, 76:19, 102:19, 103:7, 103:23, 104:24, 105:1, 105:8, 105:15, 105:19, 105:23, 201:18, 229:8, 229:16, 230:1, 251:6, 252:2, 269:19, 278:25</p> <p>Reporter [6] - 6:17, 6:18, 278:19, 279:3</p> <p>REPORTER [8] - 72:10, 72:13, 72:15, 90:2, 215:21, 215:24, 262:20, 277:9</p> <p>reporters [1] - 43:5</p> <p>Reporting [1] - 163:19</p> <p>reporting [18] - 61:17, 65:7, 77:1, 103:12, 103:13, 103:14, 103:15, 103:16, 166:19, 208:10, 242:2, 253:11, 275:17, 275:19, 276:21</p> <p>Reports [4] - 174:24, 206:3, 206:16, 259:12</p> <p>reports [18] - 61:24, 64:11, 65:8, 75:19, 146:14, 147:15, 147:16, 164:3, 164:6, 164:8, 164:13, 164:25, 190:15, 211:3, 211:4, 212:3, 212:9, 237:23</p> <p>represent [6] - 54:6, 54:11, 56:1, 63:1, 87:22, 92:16</p> <p>representatives [1] - 140:13</p> <p>represents [2] - 27:12,</p>	<p>51:1</p> <p>reps [1] - 140:17</p> <p>request [5] - 33:2, 38:3, 71:16, 96:7, 167:3</p> <p>requested [3] - 114:14, 128:25, 167:1</p> <p>Requests [1] - 9:1</p> <p>requests [1] - 210:19</p> <p>require [3] - 53:11, 191:3, 236:1</p> <p>required [10] - 20:18, 61:18, 131:20, 168:20, 169:4, 177:15, 200:1, 201:19, 249:24, 270:12</p> <p>requirement [15] - 117:18, 164:7, 203:18, 217:1, 252:15, 254:5, 255:6, 258:2, 267:22, 268:1, 268:5, 268:11, 269:4, 269:7, 269:22</p> <p>requirements [4] - 43:17, 116:18, 149:7, 270:8</p> <p>requires [4] - 32:5, 233:9, 264:24, 265:16</p> <p>research [7] - 23:3, 126:9, 127:21, 128:1, 129:18, 133:4, 180:14</p> <p>researchers [1] - 17:8</p> <p>researches [1] - 17:16</p> <p>reserve [3] - 31:9, 32:21, 33:11</p> <p>resolution [1] - 23:2</p> <p>resolve [1] - 132:12</p> <p>resolved [1] - 205:7</p> <p>resolves [1] - 89:22</p> <p>resources [1] - 185:2</p> <p>respect [2] - 135:19, 264:19</p> <p>respectfully [1] - 233:21</p> <p>respond [3] - 52:9, 85:24, 184:24</p> <p>response [3] - 131:9, 131:12, 264:18</p> <p>responses [2] - 35:17, 42:11</p> <p>responsibilities [7] - 15:4, 36:10, 132:21, 156:10, 167:23, 175:7, 216:14</p> <p>responsibility [15] -</p>	<p>117:1, 122:24, 123:1, 123:19, 132:1, 132:6, 132:14, 132:17, 133:2, 133:5, 135:3, 160:9, 216:8, 216:11, 251:21</p> <p>responsible [5] - 54:8, 54:12, 116:16, 152:20, 196:9</p> <p>rest [1] - 99:12</p> <p>restricted [2] - 20:16, 172:23</p> <p>restrictions [1] - 16:8</p> <p>restricts [1] - 245:23</p> <p>rests [1] - 159:20</p> <p>result [7] - 19:3, 20:12, 97:15, 156:16, 171:25, 258:6, 258:12</p> <p>Results [2] - 141:19</p> <p>results [9] - 32:12, 114:16, 114:18, 197:3, 211:4, 216:23, 237:25, 238:2, 240:25</p> <p>resume [3] - 44:4, 113:21, 199:5</p> <p>resumed [1] - 113:20</p> <p>retail [10] - 68:13, 69:5, 70:12, 106:24, 271:15, 271:20, 272:4, 272:8, 272:17, 273:12</p> <p>retention [1] - 269:22</p> <p>retired [1] - 12:23</p> <p>retirement [3] - 12:19, 12:20, 124:5</p> <p>retiring [1] - 12:22</p> <p>retrospect [1] - 272:12</p> <p>returned [1] - 15:16</p> <p>reveal [1] - 23:14</p> <p>review [29] - 26:11, 44:8, 59:6, 67:21, 81:4, 85:9, 102:4, 102:18, 102:22, 103:6, 106:24, 119:21, 135:1, 145:11, 163:10, 171:3, 188:19, 197:3, 206:19, 210:22, 214:13, 227:25, 228:4, 228:7, 228:8, 228:17, 228:19, 244:23, 254:16</p> <p>reviewed [21] - 23:12, 26:7, 41:11, 41:14, 41:16, 41:22, 42:8, 50:10, 109:21,</p>	<p>126:18, 127:8, 140:12, 151:1, 182:9, 196:24, 197:2, 214:17, 215:12, 223:14, 228:9, 228:11</p> <p>reviewing [8] - 24:12, 26:21, 36:2, 82:2, 129:17, 139:14, 150:13, 261:5</p> <p>reviews [4] - 19:6, 135:6, 276:22, 277:1</p> <p>revocation [1] - 170:24</p> <p>revocations [1] - 170:11</p> <p>revoked [1] - 168:14</p> <p>Reynolds [1] - 192:15</p> <p>Rice [5] - 2:9, 3:14, 4:3, 4:5, 4:8</p> <p>right-hand [4] - 66:19, 67:16, 71:19, 179:25</p> <p>rigorous [1] - 15:15</p> <p>rising [2] - 181:11, 246:5</p> <p>Rite [7] - 106:2, 106:3, 106:4, 106:9, 106:13, 136:4, 215:19</p> <p>Rite-Aid [1] - 136:4</p> <p>RMR [2] - 6:17, 6:18</p> <p>road [1] - 246:13</p> <p>roadmap [2] - 13:5, 36:24</p> <p>robberies [1] - 194:22</p> <p>robbery [1] - 194:16</p> <p>Robbery [1] - 194:18</p> <p>ROBERT [1] - 6:11</p> <p>Robert [1] - 121:20</p> <p>ROBERTSON [1] - 3:6</p> <p>rogue [1] - 39:7</p> <p>role [10] - 15:2, 29:18, 123:2, 147:2, 147:11, 148:17, 148:20, 148:23, 185:8, 185:12</p> <p>roles [2] - 148:20, 175:7</p> <p>rolled [2] - 124:6, 276:15</p> <p>Romulus [4] - 11:6, 11:7, 11:9, 12:5</p> <p>Ron [1] - 261:6</p> <p>room [1] - 174:3</p> <p>Rosenberg [1] - 183:1</p> <p>round [3] - 53:1, 53:3, 188:2</p> <p>routinely [1] - 260:17</p> <p>Roxicet [1] - 71:4</p> <p>RPR [1] - 6:18</p>	<p>RPR-RMR-CRR-FCRR [1] - 6:18</p> <p>RUBY [1] - 4:17</p> <p>Ruby [1] - 4:17</p> <p>rule [11] - 82:15, 119:25, 127:4, 135:18, 159:14, 159:16, 205:16, 228:15, 240:13, 240:22</p> <p>Rule [3] - 9:7, 53:11, 53:14</p> <p>ruled [2] - 265:4, 265:7</p> <p>rules [2] - 131:24, 249:5</p> <p>ruling [12] - 30:19, 32:21, 33:12, 37:4, 43:12, 85:6, 108:8, 236:24, 237:1, 252:9, 265:6, 265:10</p> <p>rulings [2] - 37:3, 39:16</p> <p>run [18] - 67:9, 67:10, 86:9, 86:10, 87:2, 89:16, 95:23, 98:15, 115:1, 164:18, 170:19, 210:8, 210:10, 212:14, 236:8, 237:16, 237:17, 240:16</p> <p>running [7] - 49:15, 68:12, 85:25, 96:11, 112:11, 114:6, 243:4</p> <p>runs [3] - 270:20, 275:2</p> <p>Rx [1] - 60:24</p>
S				
<p>s/Ayme [1] - 279:2</p> <p>s/Lisa [1] - 279:2</p> <p>Safety [1] - 13:1</p> <p>safety [2] - 162:11, 261:14</p> <p>sale [2] - 48:21, 143:2</p> <p>sales [11] - 27:14, 48:1, 48:6, 49:8, 140:12, 140:17, 141:23, 199:24, 201:19, 201:20, 236:1</p> <p>SALGADO [1] - 4:15</p> <p>sample [1] - 175:15</p> <p>San [2] - 2:5, 2:17</p> <p>sand [1] - 270:20</p> <p>sat [1] - 23:10</p> <p>save [1] - 107:16</p> <p>saw [3] - 23:5, 172:25, 263:8</p>				

<p>SC [3] - 3:15, 4:4, 4:9</p> <p>Scenario [3] - 89:3, 97:19, 97:25</p> <p>scenario [1] - 205:5</p> <p>Schedule [4] - 61:19, 119:8, 180:10</p> <p>Schein [3] - 154:2, 154:4, 155:6</p> <p>schemes [1] - 195:18</p> <p>SCHMIDT [165] - 5:9, 7:19, 8:13, 13:11, 30:16, 31:3, 32:14, 34:21, 39:15, 40:2, 40:9, 40:14, 51:17, 52:24, 62:8, 62:11, 62:17, 63:5, 65:10, 73:18, 78:1, 89:25, 90:4, 91:10, 91:12, 91:18, 99:3, 106:16, 108:19, 111:5, 111:8, 112:10, 112:14, 112:20, 115:9, 115:13, 118:10, 118:12, 119:10, 119:19, 120:1, 120:4, 124:20, 124:21, 125:24, 126:3, 126:19, 126:24, 127:5, 127:7, 127:12, 127:15, 128:10, 138:18, 138:23, 139:5, 139:10, 145:14, 147:9, 147:19, 147:21, 152:10, 154:18, 155:1, 155:4, 160:17, 161:2, 161:3, 165:3, 165:10, 165:15, 165:23, 166:7, 172:18, 172:21, 174:7, 174:12, 174:22, 178:12, 187:19, 188:1, 189:22, 189:25, 190:11, 190:12, 190:17, 190:20, 190:24, 192:3, 192:8, 193:1, 193:4, 197:8, 197:10, 197:18, 197:23, 198:1, 198:3, 198:6, 199:1, 199:6, 199:7, 200:18, 200:24, 202:21, 203:1, 203:3, 207:15, 207:21, 209:7, 211:23, 211:25, 214:1, 214:4, 214:5,</p>	<p>215:23, 215:25, 216:2, 217:21, 217:25, 218:25, 219:4, 221:11, 221:17, 221:19, 221:22, 221:25, 230:21, 231:2, 232:3, 232:4, 233:17, 233:23, 234:5, 234:10, 234:13, 234:16, 234:18, 234:19, 235:13, 238:8, 238:12, 243:14, 243:17, 246:14, 246:15, 256:12, 256:18, 262:18, 262:24, 263:20, 264:3, 264:4, 267:5, 267:9, 267:11, 270:15, 270:21, 270:25, 277:11, 277:15, 277:17, 277:21, 277:25, 278:10</p> <p>Schmidt [30] - 31:10, 31:21, 39:14, 40:12, 51:16, 52:23, 62:7, 73:17, 89:24, 91:17, 115:16, 122:22, 126:23, 135:5, 147:7, 155:3, 157:19, 171:4, 171:16, 182:17, 189:20, 193:19, 199:5, 204:3, 207:14, 240:6, 241:11, 277:20, 278:5, 278:7</p> <p>Schmidt's [2] - 14:5, 62:25</p> <p>scientific [1] - 180:14</p> <p>scope [11] - 9:6, 44:15, 44:19, 52:18, 85:19, 86:16, 119:20, 126:22, 145:17, 147:1, 207:12</p> <p>screen [20] - 29:23, 53:23, 97:15, 98:16, 120:5, 120:11, 138:24, 142:8, 146:20, 162:23, 163:9, 186:20, 198:4, 202:13, 218:25, 230:23, 238:11, 239:2, 256:16, 267:10</p> <p>scrutiny [2] - 121:6, 182:8</p>	<p>search [3] - 16:7, 20:16, 167:1</p> <p>searches [2] - 114:6, 115:1</p> <p>seat [3] - 10:10, 63:14, 76:21</p> <p>second [31] - 9:10, 13:18, 23:22, 58:8, 59:25, 62:21, 65:4, 71:11, 75:1, 92:18, 117:8, 117:15, 118:20, 120:13, 139:18, 143:9, 174:10, 175:4, 180:7, 181:11, 182:24, 198:4, 200:23, 231:20, 246:20, 256:20, 257:3, 260:1, 260:3, 269:8, 269:9</p> <p>Second [1] - 27:16</p> <p>second-guess [2] - 117:8, 117:15</p> <p>secondly [1] - 29:2</p> <p>section [6] - 14:25, 44:6, 93:2, 163:18, 168:6, 168:7</p> <p>Section [2] - 274:6, 274:22</p> <p>sectors [2] - 258:5, 258:11</p> <p>security [1] - 30:3</p> <p>see [196] - 7:13, 9:11, 14:2, 14:16, 20:17, 25:22, 29:2, 52:5, 54:2, 55:4, 57:2, 57:12, 58:6, 66:23, 67:4, 67:16, 67:19, 68:3, 70:21, 88:13, 92:5, 94:16, 97:15, 113:12, 115:14, 118:14, 118:16, 118:17, 118:19, 118:20, 118:23, 119:1, 119:3, 120:11, 120:19, 120:20, 124:23, 124:25, 125:3, 125:5, 125:6, 125:10, 125:12, 125:13, 125:14, 125:21, 126:12, 138:25, 139:11, 139:15, 139:17, 139:20, 140:1, 140:8, 140:13, 141:5, 141:6, 141:10, 141:11, 142:7, 142:14, 142:15, 142:23,</p>	<p>143:6, 143:11, 147:17, 147:22, 148:3, 148:7, 148:8, 151:25, 153:13, 163:17, 163:19, 163:24, 166:16, 166:17, 168:3, 168:9, 168:14, 168:22, 169:25, 170:6, 170:7, 170:13, 170:14, 172:3, 172:4, 172:14, 172:22, 172:23, 175:4, 175:12, 176:10, 177:20, 178:7, 180:3, 180:5, 181:9, 181:12, 181:21, 182:3, 183:3, 183:5, 183:6, 185:4, 188:24, 189:2, 193:7, 193:14, 193:16, 193:19, 193:21, 193:22, 194:7, 194:11, 194:13, 195:7, 195:12, 195:18, 196:15, 197:12, 197:14, 198:7, 198:13, 201:1, 201:4, 201:7, 201:8, 201:23, 203:4, 212:19, 212:22, 213:1, 213:2, 215:16, 219:13, 219:16, 225:14, 227:25, 228:22, 229:14, 229:16, 229:22, 231:3, 231:7, 231:16, 231:18, 231:22, 232:11, 232:19, 237:17, 237:25, 241:14, 241:15, 249:12, 254:16, 256:22, 256:23, 257:6, 257:24, 258:13, 258:17, 259:12, 259:13, 260:20, 261:5, 261:18, 263:1, 264:9, 264:13, 264:20, 264:24, 264:25, 265:13, 265:15, 265:16, 265:18, 266:3, 266:4, 266:7, 266:9, 266:10, 266:14, 266:15, 267:12, 267:21, 267:24, 271:2, 275:16,</p>	<p>276:21, 276:23, 278:3, 278:13</p> <p>seeing [1] - 154:6</p> <p>seem [2] - 31:20, 157:14</p> <p>segment [1] - 92:25</p> <p>self [5] - 106:13, 135:15, 135:21, 136:1, 136:6</p> <p>self-distribute [2] - 135:21, 136:6</p> <p>self-distributes [1] - 136:1</p> <p>self-distributing [1] - 135:15</p> <p>self-distribution [1] - 106:13</p> <p>sell [3] - 19:14, 80:17, 144:4</p> <p>selling [1] - 196:9</p> <p>seminar [1] - 261:7</p> <p>sending [2] - 20:7, 20:10</p> <p>Senior [1] - 7:2</p> <p>SENIOR [1] - 1:17</p> <p>Sensabaugh [1] - 5:14</p> <p>sent [6] - 64:21, 73:11, 144:22, 158:16, 164:13, 164:25</p> <p>sentence [19] - 53:14, 141:20, 143:1, 163:24, 166:12, 166:21, 171:5, 172:8, 180:7, 181:11, 181:14, 198:10, 203:5, 256:20, 257:3, 260:3, 267:20, 267:21, 268:4</p> <p>September [16] - 15:10, 118:15, 186:19, 188:22, 211:23, 212:22, 221:6, 228:21, 229:13, 235:10, 260:14, 261:17, 261:18, 262:5, 263:2, 268:23</p> <p>sergeant [2] - 11:13, 11:14</p> <p>series [2] - 147:13, 175:15</p> <p>serve [2] - 16:7, 188:3</p> <p>served [1] - 23:15</p> <p>service [1] - 84:11</p> <p>serviced [1] - 69:5</p> <p>services [1] - 58:25</p> <p>servicing [1] - 69:10</p> <p>serving [1] - 196:23</p> <p>set [14] - 75:16, 80:14,</p>
--	---	--	---	---

<p>80:21, 82:19, 82:20, 89:15, 92:21, 92:22, 97:14, 99:24, 180:17, 236:9, 272:7, 272:19</p> <p>sets [2] - 92:22, 247:1</p> <p>setting [5] - 87:15, 180:24, 181:4, 249:2, 249:15</p> <p>settle [1] - 22:1</p> <p>seven [7] - 87:25, 88:12, 88:21, 90:16, 90:18, 270:19, 270:22</p> <p>seven-month [1] - 87:25</p> <p>seventh [3] - 89:1, 89:14, 89:15</p> <p>several [5] - 84:20, 137:8, 171:18, 213:12, 226:5</p> <p>severance [1] - 154:12</p> <p>severing [2] - 147:4, 254:24</p> <p>SHANNON [1] - 6:3</p> <p>share [3] - 137:6, 178:7, 191:3</p> <p>sharing [1] - 191:2</p> <p>sharp [1] - 57:2</p> <p>Sheriff's [3] - 11:1, 11:3, 11:6</p> <p>shift [3] - 12:12, 55:14, 231:25</p> <p>shifted [3] - 55:6, 55:17, 231:25</p> <p>shifts [2] - 241:17, 241:23</p> <p>ship [34] - 24:19, 61:4, 61:5, 75:18, 76:8, 79:15, 79:18, 91:15, 148:13, 159:17, 160:14, 161:6, 161:11, 161:21, 203:17, 235:7, 251:15, 251:24, 252:15, 253:11, 254:5, 254:9, 255:6, 255:8, 258:2, 259:12, 261:11, 261:12, 261:16, 268:1, 268:11, 269:4, 269:7</p> <p>shipment [10] - 75:11, 103:12, 103:13, 103:14, 103:15, 103:16, 159:15, 208:7</p> <p>shipments [6] - 137:6, 220:5, 220:7, 257:23, 260:16,</p>	<p>273:17</p> <p>shipped [15] - 61:2, 71:25, 73:2, 76:25, 89:9, 94:1, 95:1, 97:16, 130:9, 131:7, 150:23, 206:22, 206:23, 217:4, 251:11</p> <p>shipping [8] - 28:20, 65:6, 72:3, 103:12, 159:15, 226:23, 267:22, 267:23</p> <p>Shoppe [4] - 67:5, 70:23, 71:25, 72:22</p> <p>shopping [1] - 195:7</p> <p>short [3] - 53:13, 201:22, 274:12</p> <p>shorten [2] - 40:6, 99:18</p> <p>shorthand [1] - 230:3</p> <p>show [22] - 25:10, 36:5, 55:7, 55:18, 86:10, 99:5, 112:16, 138:11, 162:19, 168:1, 190:14, 197:4, 204:22, 211:10, 212:1, 218:23, 230:17, 231:1, 238:2, 241:3, 250:20, 267:16</p> <p>Show [2] - 21:1, 39:10</p> <p>showed [4] - 85:17, 206:1, 208:14, 278:5</p> <p>showing [2] - 175:15, 194:2</p> <p>shown [3] - 122:1, 221:10, 232:11</p> <p>shows [2] - 175:18, 182:2</p> <p>sic [1] - 142:1</p> <p>side [2] - 188:7, 201:25</p> <p>signature [4] - 147:22, 147:24, 147:25, 148:3</p> <p>significant [2] - 275:4, 275:9</p> <p>significantly [1] - 45:22</p> <p>similar [16] - 12:15, 20:16, 21:18, 36:9, 36:16, 59:13, 73:20, 131:6, 160:16, 209:20, 209:24, 223:7, 235:7, 238:16, 243:7, 246:21</p> <p>similarity [1] - 60:8</p> <p>similarly [2] - 121:21, 210:9</p>	<p>simple [4] - 60:23, 160:20, 234:1, 265:12</p> <p>simply [6] - 42:4, 45:21, 51:3, 234:5, 237:19, 240:13</p> <p>SINGER [1] - 4:5</p> <p>single [9] - 77:16, 95:13, 128:12, 129:8, 147:12, 220:9, 232:21, 232:24, 278:1</p> <p>sit [6] - 40:10, 123:2, 215:15, 251:7, 256:2, 256:3</p> <p>site [6] - 22:22, 28:7, 28:10, 160:13, 169:11, 276:20</p> <p>sites [1] - 164:6</p> <p>sitting [1] - 8:22</p> <p>situations [1] - 158:3</p> <p>six [38] - 17:25, 85:4, 85:7, 87:18, 87:21, 88:1, 88:4, 88:7, 88:17, 89:19, 90:15, 90:19, 92:12, 92:13, 210:13, 212:10, 219:5, 224:23, 230:15, 231:15, 231:16, 231:18, 231:20, 231:21, 232:10, 232:25, 233:3, 233:5, 236:25, 245:18, 246:6, 246:10, 246:16, 246:22, 246:24, 247:7, 247:8</p> <p>six-month [5] - 85:4, 85:7, 87:18, 230:15, 236:25</p> <p>sixth [6] - 87:24, 94:22, 94:23, 160:2, 231:10, 247:15</p> <p>size [6] - 82:25, 203:5, 204:8, 204:13, 204:19, 205:9</p> <p>skip [1] - 15:8</p> <p>sleeping [1] - 18:22</p> <p>slide [64] - 13:13, 14:12, 27:1, 27:4, 27:8, 33:23, 34:1, 34:5, 35:25, 36:2, 36:6, 37:11, 41:21, 44:18, 44:21, 45:5, 45:6, 47:8, 47:10, 50:15, 50:25, 51:1, 51:9, 51:11, 51:19, 51:22, 51:24, 55:7, 56:16, 58:12, 59:17, 59:18, 60:12, 60:18,</p>	<p>60:21, 63:7, 64:5, 75:2, 81:17, 82:1, 82:5, 82:9, 87:9, 94:21, 103:1, 104:14, 105:17, 176:21, 176:22, 224:21, 224:22, 225:19, 238:9, 243:19, 243:21, 243:24, 246:16, 252:7, 271:13, 271:14, 273:4</p> <p>Slide [14] - 44:7, 44:24, 47:14, 50:22, 56:17, 58:13, 58:14, 60:17, 96:8, 219:2, 243:15, 246:14, 265:23</p> <p>Slides [1] - 99:1</p> <p>slides [13] - 13:6, 13:12, 13:20, 13:22, 13:25, 14:6, 50:18, 51:25, 53:3, 99:12, 220:11, 243:14, 263:8</p> <p>slog [1] - 82:10</p> <p>slow [2] - 184:24, 215:21</p> <p>small [5] - 78:17, 120:17, 270:16, 270:17, 274:13</p> <p>smaller [4] - 18:7, 80:19, 84:6, 84:7</p> <p>smallest [1] - 80:18</p> <p>Smith [4] - 6:4, 6:11, 264:10, 264:18</p> <p>Smith's [1] - 234:11</p> <p>smoking [1] - 18:23</p> <p>sold [3] - 54:24, 144:16, 170:2</p> <p>sole [1] - 155:12</p> <p>someone [8] - 125:21, 158:17, 167:3, 196:14, 198:12, 199:15, 225:5, 236:11</p> <p>sometime [2] - 39:3, 74:16</p> <p>sometimes [7] - 19:13, 24:1, 24:4, 42:20, 94:23, 161:17, 210:1</p> <p>Sometimes [2] - 18:23, 195:13</p> <p>somewhere [2] - 60:5, 215:20</p> <p>SOMS [12] - 27:22, 37:15, 37:17, 42:15, 54:16, 65:4, 81:24, 146:8, 146:18,</p>	<p>148:5, 148:6, 275:13</p> <p>sooner [1] - 252:10</p> <p>sophisticated [1] - 19:9</p> <p>Sorry [1] - 197:8</p> <p>sorry [56] - 15:24, 20:5, 62:9, 69:16, 69:20, 72:19, 78:1, 86:12, 86:13, 90:2, 90:4, 90:22, 100:9, 103:18, 104:21, 105:5, 105:11, 108:14, 110:21, 114:9, 133:20, 141:1, 141:21, 142:19, 149:25, 150:6, 152:8, 152:13, 153:3, 155:2, 164:1, 173:2, 173:13, 175:14, 179:23, 184:2, 186:1, 202:17, 208:2, 212:1, 215:6, 215:21, 215:23, 221:7, 221:23, 240:20, 244:14, 254:10, 257:2, 258:8, 258:9, 262:14, 262:20, 263:16, 277:9, 277:18</p> <p>SORS [4] - 166:13, 166:15, 166:18, 167:12</p> <p>sorted [1] - 72:15</p> <p>sought [1] - 257:4</p> <p>sound [1] - 206:4</p> <p>source [2] - 19:11, 250:15</p> <p>south [1] - 248:13</p> <p>South [2] - 2:13, 20:11</p> <p>Southern [1] - 7:3</p> <p>SOUTHERN [1] - 1:1</p> <p>Southwood [12] - 37:3, 39:5, 39:6, 40:18, 40:19, 252:4, 252:6, 266:4, 268:5, 268:11, 268:12, 269:2</p> <p>speaking [8] - 80:19, 133:25, 134:10, 171:9, 201:5, 239:15, 249:23, 258:9</p> <p>speaks [2] - 82:23, 166:25</p> <p>Special [2] - 11:16, 11:24</p> <p>special [1] - 11:17</p> <p>specialists [1] -</p>
---	--	--	---	--

<p>141:25</p> <p>specialty [1] - 271:21</p> <p>specific [27] - 15:20, 24:8, 32:13, 38:18, 42:11, 67:3, 71:2, 73:19, 94:15, 130:5, 130:20, 133:8, 135:1, 145:19, 160:22, 176:2, 176:24, 179:10, 189:18, 192:19, 206:24, 207:3, 218:15, 218:18, 218:19, 269:21, 270:8</p> <p>specifically [24] - 20:8, 40:1, 59:7, 78:13, 119:4, 120:14, 130:10, 132:3, 132:23, 137:9, 144:23, 153:18, 171:10, 171:11, 180:19, 226:21, 237:16, 248:25, 251:14, 265:23, 266:25, 269:25, 270:6, 276:25</p> <p>Specifically [1] - 166:25</p> <p>specificity [1] - 247:25</p> <p>spectrum [1] - 187:1</p> <p>speed [2] - 40:4, 81:14</p> <p>spent [4] - 21:11, 115:15, 191:20, 192:22</p> <p>split [2] - 123:24, 252:4</p> <p>sponsor [1] - 52:1</p> <p>sponsored [2] - 214:22, 265:22</p> <p>Square [2] - 6:5, 6:12</p> <p>square [1] - 66:24</p> <p>staff [5] - 164:6, 164:7, 166:14, 167:12, 169:22</p> <p>stage [3] - 78:24, 78:25, 84:14</p> <p>stalling [1] - 43:6</p> <p>stamp [1] - 66:15</p> <p>stand [4] - 74:10, 91:21, 113:22, 144:2</p> <p>standard [1] - 259:11</p> <p>standards [1] - 43:24</p> <p>standing [3] - 159:14, 162:5, 185:9</p> <p>stands [1] - 27:23</p> <p>Stanner [1] - 9:8</p> <p>STANNER [2] - 5:10, 9:9</p>	<p>start [20] - 10:24, 11:15, 11:19, 22:16, 47:23, 54:2, 61:10, 87:17, 110:5, 115:23, 116:14, 141:21, 163:22, 179:22, 183:16, 188:25, 205:3, 257:2, 257:3, 270:16</p> <p>started [12] - 11:5, 11:12, 11:17, 11:24, 22:15, 23:13, 231:5, 246:6, 253:3, 255:1, 274:14</p> <p>starting [9] - 55:10, 56:18, 80:5, 112:22, 124:5, 250:24, 265:7, 276:9, 276:12</p> <p>starts [2] - 67:4, 87:21</p> <p>state [15] - 9:17, 10:5, 10:17, 18:9, 74:7, 78:21, 116:25, 121:6, 144:6, 150:8, 171:19, 171:22, 171:24, 175:20, 176:25</p> <p>State [3] - 92:25, 209:1, 209:16</p> <p>Statement [1] - 119:1</p> <p>statement [104] - 9:6, 73:12, 97:18, 116:11, 116:24, 117:17, 118:6, 119:4, 119:9, 119:18, 120:22, 120:25, 121:9, 122:4, 122:7, 123:15, 125:9, 125:15, 125:18, 129:7, 129:13, 134:3, 134:4, 135:5, 135:13, 137:11, 141:12, 142:6, 143:16, 144:7, 144:10, 144:14, 144:18, 144:21, 145:24, 149:2, 149:5, 149:13, 155:8, 155:14, 156:14, 156:18, 156:21, 156:24, 157:3, 157:19, 159:24, 161:8, 161:19, 161:24, 161:25, 162:18, 164:12, 164:24, 165:25, 168:16, 168:24, 169:1, 169:7, 169:15, 170:16, 171:13,</p>	<p>173:4, 177:17, 178:23, 181:25, 187:18, 187:21, 187:23, 188:8, 188:11, 198:22, 200:12, 201:8, 204:15, 205:7, 206:25, 208:5, 208:12, 209:25, 211:1, 218:20, 221:12, 221:14, 229:23, 231:14, 234:23, 235:9, 236:15, 236:18, 236:23, 237:5, 241:22, 242:5, 244:22, 245:16, 250:12, 253:25, 254:7, 254:9, 255:2, 256:23, 257:16, 269:5</p> <p>statements [2] - 118:3, 118:8</p> <p>STATES [2] - 1:1, 1:17</p> <p>states [5] - 163:22, 201:1, 223:23, 256:20</p> <p>States [10] - 7:2, 21:24, 121:22, 122:10, 150:11, 156:2, 165:19, 180:15, 253:19, 254:24</p> <p>stating [1] - 97:10</p> <p>statistic [3] - 196:19, 198:15, 199:12</p> <p>statistical [2] - 275:7, 276:8</p> <p>statistical/non [1] - 275:7</p> <p>statistical/non-statistical [1] - 275:7</p> <p>statistics [2] - 196:12, 196:15</p> <p>STATUS [1] - 1:17</p> <p>Status [1] - 7:2</p> <p>statute [1] - 255:9</p> <p>statutes [1] - 255:7</p> <p>stay [1] - 52:7</p> <p>steep [2] - 55:2, 55:4</p> <p>stenography [1] - 6:19</p> <p>step [9] - 43:9, 60:21, 63:3, 63:4, 73:25, 75:2, 91:2, 95:9</p> <p>steps [2] - 14:16, 23:15</p> <p>STEVEN [1] - 4:17</p> <p>stick [2] - 55:20, 55:22</p> <p>stickers [1] - 21:12</p> <p>still [13] - 8:22, 19:10,</p>	<p>113:22, 117:6, 151:7, 151:9, 179:19, 205:4, 233:5, 234:21, 236:25, 239:14, 248:7</p> <p>stips [1] - 8:24</p> <p>stipulated [1] - 154:12</p> <p>stipulation [1] - 147:4</p> <p>stone [1] - 239:10</p> <p>stood [1] - 259:23</p> <p>stop [15] - 13:2, 21:4, 23:22, 71:11, 72:5, 72:8, 88:2, 88:22, 89:2, 89:14, 91:9, 95:7, 150:9, 277:22</p> <p>stopped [5] - 28:19, 77:14, 78:14, 94:9, 158:10</p> <p>stopping [1] - 198:25</p> <p>stops [1] - 75:22</p> <p>stored [1] - 21:9</p> <p>stores [4] - 106:5, 106:9, 106:14, 136:24</p> <p>straight [3] - 25:21, 93:19, 115:17</p> <p>straighten [1] - 189:24</p> <p>straightening [1] - 189:20</p> <p>Strategy [1] - 124:24</p> <p>street [1] - 205:1</p> <p>Street [15] - 2:7, 2:10, 2:13, 3:5, 3:7, 3:10, 3:12, 4:6, 4:13, 4:15, 4:18, 5:5, 5:12, 6:6, 6:13</p> <p>strike [5] - 107:12, 107:18, 165:23, 166:5, 234:12</p> <p>striking [1] - 166:2</p> <p>strong [1] - 23:7</p> <p>studied [2] - 66:10, 192:21</p> <p>studies [1] - 205:12</p> <p>study [3] - 139:11, 169:17, 192:19</p> <p>studying [2] - 16:13, 137:25</p> <p>style [2] - 223:12, 256:21</p> <p>stylized [6] - 220:22, 222:1, 222:5, 223:13, 223:18, 224:12</p> <p>sub [1] - 19:1</p> <p>subject [8] - 30:19, 32:22, 33:10, 43:23, 44:2, 189:19, 203:16, 203:20</p>	<p>submit [3] - 26:9, 61:7, 99:1</p> <p>submitted [3] - 64:11, 200:3, 201:2</p> <p>subpoena [2] - 23:16, 28:11</p> <p>subsequent [5] - 77:23, 89:7, 97:12, 97:21, 241:10</p> <p>subset [1] - 19:20</p> <p>substance [1] - 156:22</p> <p>substances [33] - 16:16, 17:5, 21:14, 22:24, 27:15, 28:16, 29:1, 30:2, 30:6, 30:12, 38:19, 38:22, 42:14, 44:12, 48:14, 55:16, 75:10, 104:5, 107:10, 117:2, 120:16, 120:24, 121:5, 134:18, 136:9, 142:24, 143:3, 155:20, 180:10, 183:1, 185:3, 236:2, 272:12</p> <p>Substances [1] - 118:22</p> <p>substantial [4] - 97:16, 110:25, 111:20, 181:15</p> <p>substantially [2] - 82:25, 203:6</p> <p>substitute [1] - 36:13</p> <p>sudden [1] - 55:18</p> <p>suddenly [1] - 204:18</p> <p>sufficient [5] - 102:14, 106:4, 106:8, 106:23, 265:8</p> <p>sufficiently [1] - 106:13</p> <p>Suffolk [2] - 208:25, 209:14</p> <p>suggest [1] - 113:15</p> <p>suggested [1] - 78:24</p> <p>suggestive [1] - 31:18</p> <p>suing [2] - 116:5, 223:22</p> <p>Suite [9] - 2:4, 2:7, 2:10, 2:13, 2:16, 3:17, 4:6, 6:5, 6:12</p> <p>summaries [1] - 42:12</p> <p>summarize [1] - 40:4</p> <p>summarizing [2] - 68:19, 68:20</p> <p>summary [2] - 7:17, 7:18</p> <p>summation [1] - 261:7</p> <p>Summit [4] - 208:23, 209:10, 210:18,</p>
---	--	---	---	--

<p>211:20 supervisor [2] - 22:6, 260:12 supplied [4] - 151:23, 152:1, 173:8, 173:12 supplier [1] - 152:17 supply [6] - 19:11, 148:18, 149:21, 150:14, 185:23, 193:5 supplying [2] - 131:22, 159:23 Support [3] - 248:23, 248:25, 249:13 supported [1] - 39:2 supposed [8] - 76:1, 87:19, 116:20, 117:15, 132:8, 180:16, 180:20, 238:15 surgery [1] - 218:3 surround [1] - 11:11 suspect [1] - 233:24 suspend [2] - 257:23, 260:16 suspended [1] - 168:14 suspension [2] - 170:24, 236:1 Suspension [2] - 20:25, 21:14 suspensions [1] - 170:10 suspicion [17] - 76:3, 76:14, 76:18, 77:1, 79:19, 79:24, 84:18, 88:24, 94:12, 97:11, 102:15, 104:10, 104:12, 217:20, 229:11, 234:25 Suspicious [18] - 24:15, 27:23, 30:5, 30:10, 37:18, 41:2, 42:15, 58:9, 60:4, 75:12, 146:9, 163:18, 192:11, 206:2, 206:16, 220:15, 259:11, 264:11 suspicious [80] - 24:18, 24:22, 28:17, 28:20, 29:3, 29:5, 42:22, 60:10, 61:16, 74:18, 76:2, 77:1, 78:10, 78:24, 78:25, 79:2, 79:21, 82:22, 83:8, 102:19, 103:7, 103:23, 103:25, 104:1, 104:7, 104:17, 104:23,</p>	<p>105:7, 105:15, 105:19, 105:22, 109:3, 112:4, 112:24, 162:17, 164:2, 164:12, 164:24, 165:21, 166:18, 167:2, 202:7, 203:4, 203:8, 203:25, 204:1, 204:2, 204:3, 204:5, 204:22, 205:18, 206:13, 208:10, 225:11, 226:22, 227:7, 228:2, 228:14, 229:9, 229:16, 230:1, 235:7, 235:25, 242:2, 249:5, 251:10, 251:15, 251:20, 257:24, 260:15, 260:17, 261:1, 261:21, 264:13, 264:20, 265:14, 267:24, 275:19, 276:22 sustain [2] - 62:13, 234:7 sustained [2] - 78:7, 209:6 SUZANNE [1] - 4:15 sweeping [1] - 73:20 switch [3] - 190:13, 218:25, 230:23 switching [1] - 269:21 sworn [1] - 165:13 SWORN [1] - 10:9 system [60] - 16:19, 16:20, 17:11, 27:23, 28:2, 28:20, 29:3, 37:19, 60:13, 62:2, 63:2, 63:4, 63:8, 74:22, 75:11, 75:17, 75:20, 75:23, 75:25, 77:12, 77:17, 79:14, 80:3, 80:6, 80:8, 80:12, 80:15, 80:22, 81:5, 83:17, 83:18, 84:10, 85:4, 85:9, 85:13, 87:24, 88:15, 90:18, 92:8, 93:12, 94:9, 94:19, 95:21, 97:13, 109:2, 133:16, 148:5, 155:17, 166:19, 193:10, 201:1, 225:11, 233:13, 246:2, 249:6, 256:22, 270:11, 276:16 System [10] - 24:16,</p>	<p>30:5, 37:18, 41:3, 58:9, 60:5, 75:12, 163:19, 174:24, 220:15 systematic [1] - 26:14 systemic [7] - 109:9, 109:14, 109:15, 109:17, 110:24, 111:19, 228:15 Systems [2] - 30:10, 42:16 systems [9] - 42:15, 62:19, 83:2, 83:8, 83:20, 83:22, 85:16, 97:24, 245:23</p> <p style="text-align: center;">T</p> <p>tab [2] - 146:21, 200:21 Tab [1] - 200:21 table [1] - 152:11 tablets [11] - 20:11, 48:19, 48:20, 48:24, 49:2, 49:9, 49:10, 49:23, 49:24, 56:22, 98:11 tabs [2] - 71:14, 71:17 taint [1] - 122:18 talks [6] - 139:14, 143:8, 143:13, 167:5, 170:2, 181:11 target [1] - 272:18 targeted [2] - 28:12, 115:18 targeting [1] - 38:12 Targeting [1] - 175:5 Task [4] - 12:5, 12:6, 15:8, 18:3 tasked [2] - 20:5, 134:20 technical [2] - 82:12, 96:4 techniques [1] - 248:18 TEMITOPE [1] - 4:8 temporal [3] - 44:15, 44:19, 237:19 tempted [1] - 236:24 ten [5] - 48:19, 80:14, 80:17, 205:23, 276:6 Ten [1] - 159:3 ten-percent [1] - 276:6 tendered [1] - 34:20 tendering [1] - 42:5 tens [6] - 214:7, 214:10, 228:5, 229:8, 229:15, 229:25 Tenth [1] - 5:12</p>	<p>tenth [2] - 122:10, 122:15 term [7] - 18:20, 26:14, 133:8, 133:11, 220:24, 221:1, 263:21 terminology [1] - 93:8 terms [18] - 80:9, 109:21, 117:11, 127:16, 134:21, 181:4, 184:2, 184:4, 210:12, 216:14, 230:9, 237:22, 242:4, 244:3, 251:12, 251:17, 264:19, 277:16 test [2] - 87:17, 96:14 testified [28] - 86:7, 103:3, 121:21, 130:12, 137:2, 146:3, 150:18, 150:19, 190:8, 210:7, 212:2, 213:8, 236:4, 236:23, 252:22, 253:10, 253:13, 254:1, 254:4, 254:14, 255:6, 255:18, 255:21, 256:9, 259:10, 264:10, 264:18, 265:14 testifies [1] - 212:23 testify [11] - 13:7, 16:2, 43:22, 51:21, 52:12, 66:1, 137:14, 210:3, 254:2, 256:2 testifying [13] - 13:24, 65:20, 68:16, 122:5, 123:21, 157:9, 165:4, 165:16, 165:25, 166:8, 223:20, 252:17, 261:24 testimony [97] - 9:5, 13:5, 13:7, 13:16, 13:21, 14:17, 31:22, 32:21, 33:11, 34:2, 36:3, 43:12, 43:15, 43:22, 44:22, 47:10, 51:24, 52:13, 54:14, 62:15, 63:11, 64:10, 65:11, 65:12, 65:20, 68:23, 73:19, 73:21, 73:24, 74:17, 76:23, 80:2, 82:6, 85:19, 86:6, 89:25, 90:6, 91:20, 107:12, 121:14, 121:16, 121:17, 121:18, 121:24, 122:1,</p>	<p>128:11, 131:1, 131:4, 137:9, 147:6, 148:4, 157:5, 157:11, 164:15, 165:7, 165:13, 165:17, 174:14, 186:18, 187:17, 201:23, 209:17, 211:10, 212:2, 212:19, 212:21, 214:20, 229:5, 233:15, 233:18, 233:25, 234:1, 234:8, 235:15, 253:4, 253:18, 255:14, 256:4, 257:4, 257:9, 257:11, 257:13, 257:14, 259:15, 259:18, 260:22, 261:17, 263:12, 264:6, 264:15, 277:2, 277:8, 277:11, 277:13 text [1] - 203:21 thankfully [1] - 235:20 THE [260] - 1:1, 1:1, 1:4, 1:17, 7:6, 7:9, 7:13, 7:23, 7:24, 8:2, 8:11, 8:18, 8:19, 9:8, 9:19, 9:23, 10:1, 10:5, 10:7, 10:8, 10:10, 10:12, 10:14, 14:2, 14:9, 14:13, 21:15, 21:17, 25:18, 25:23, 26:2, 30:15, 30:25, 31:7, 32:8, 32:18, 32:20, 33:4, 33:9, 33:17, 35:1, 35:11, 35:14, 36:17, 36:22, 36:23, 39:14, 39:24, 40:3, 40:6, 40:8, 40:11, 40:15, 40:16, 43:4, 43:7, 43:10, 43:12, 44:4, 45:1, 45:24, 46:15, 47:15, 48:3, 48:4, 48:5, 48:6, 50:23, 51:7, 51:16, 52:4, 52:8, 52:23, 53:5, 53:9, 53:13, 53:24, 59:21, 60:18, 60:22, 60:23, 62:7, 62:10, 62:13, 63:10, 63:16, 64:2, 64:3, 64:8, 65:16, 65:22, 65:24, 66:4, 66:21, 68:15, 68:21, 69:16, 69:17, 69:19, 69:20, 70:4, 70:9, 72:8, 72:11, 72:14, 72:20, 73:17,</p>
---	--	--	--	---

74:3, 74:8, 74:13, 75:4, 75:5, 75:8, 77:3, 77:25, 78:7, 78:15, 78:17, 79:4, 80:2, 80:5, 80:7, 80:9, 80:10, 81:11, 81:14, 82:13, 85:22, 86:12, 86:19, 89:24, 90:10, 90:20, 90:23, 91:1, 91:11, 91:14, 91:17, 91:24, 94:2, 94:3, 99:7, 99:10, 99:14, 99:18, 99:20, 100:9, 100:10, 105:10, 105:11, 106:19, 106:21, 107:13, 107:17, 108:9, 108:20, 108:21, 109:14, 109:15, 109:19, 109:24, 110:13, 110:15, 110:19, 110:21, 111:13, 111:15, 112:9, 112:13, 112:16, 113:9, 113:13, 113:18, 113:21, 113:25, 115:8, 115:11, 118:11, 119:12, 119:14, 119:24, 120:2, 126:23, 127:2, 127:14, 128:7, 128:9, 138:20, 138:22, 139:9, 145:6, 145:9, 145:11, 147:14, 152:9, 154:22, 155:2, 160:22, 160:24, 160:25, 165:14, 166:1, 166:4, 172:16, 172:19, 174:9, 174:21, 178:1, 178:3, 187:14, 187:21, 189:17, 189:23, 190:10, 190:18, 190:19, 190:22, 192:5, 192:7, 193:3, 197:9, 197:20, 198:2, 198:24, 199:2, 199:5, 202:18, 202:22, 203:2, 207:13, 207:14, 207:19, 207:20, 209:6, 214:3, 217:23, 221:16, 221:18, 221:24, 233:20, 234:7, 234:17, 239:8,	239:9, 256:17, 262:16, 262:22, 263:16, 263:17, 263:25, 267:8, 270:19, 277:12, 277:19, 277:23, 278:1, 278:11, 278:12, 278:13, 278:14 theft [2] - 194:16, 194:18 thefts [1] - 194:22 themselves [2] - 135:15, 135:16 theoretical [2] - 87:12, 88:12 theory [2] - 87:19, 233:13 thereafter [1] - 65:6 therefore [1] - 258:15 Therefore [1] - 168:18 they've [3] - 71:20, 181:6, 251:24 thinking [1] - 122:9 third [8] - 8:14, 45:13, 85:12, 125:13, 256:25, 264:6, 264:8, 264:9 Thomas [1] - 2:12 thousand [4] - 48:20, 85:1, 156:22, 157:21 thousands [5] - 186:13, 186:16, 187:4, 187:9, 207:9 Three [1] - 6:5 three [50] - 6:12, 8:6, 11:17, 11:23, 15:20, 29:23, 29:25, 38:6, 42:15, 42:16, 42:19, 47:20, 54:15, 56:18, 56:19, 57:24, 60:4, 62:20, 71:7, 74:17, 74:23, 80:3, 85:15, 85:25, 86:7, 93:13, 93:17, 99:22, 99:24, 100:21, 112:18, 116:2, 116:6, 116:7, 116:11, 134:15, 134:18, 139:15, 149:14, 150:25, 186:9, 194:13, 196:13, 198:11, 199:13, 206:4, 206:22, 212:3, 241:3, 274:19 three-times [1] - 85:25 Threshold [1] - 9:1 threshold [30] - 9:14, 68:1, 73:15, 75:16, 75:17, 75:21, 77:18,	83:16, 84:14, 85:4, 85:8, 87:18, 88:11, 89:16, 93:23, 94:13, 94:14, 94:16, 99:24, 226:24, 241:9, 242:23, 243:2, 243:5, 243:11, 244:21, 247:1, 251:5, 276:1, 276:22 thresholds [8] - 89:23, 106:8, 207:4, 245:19, 251:1, 276:4, 276:9, 276:11 throughout [2] - 22:12, 164:6 tied [1] - 38:16 timeline [8] - 42:17, 45:3, 54:3, 56:23, 57:7, 57:10, 58:21, 65:2 TIMOTHY [1] - 5:9 tiny [2] - 78:15, 78:17 title [1] - 15:25 today [14] - 14:17, 29:14, 29:18, 34:2, 44:22, 47:11, 117:6, 123:2, 128:3, 144:1, 216:4, 216:7, 237:15, 242:10 today's [1] - 13:5 together [5] - 25:16, 115:15, 121:16, 250:5, 251:22 Toledo [5] - 18:18, 19:2, 19:3, 128:18, 128:19 tomorrow [1] - 270:22 took [16] - 12:10, 19:5, 20:24, 21:8, 23:16, 23:19, 39:9, 68:10, 123:2, 165:11, 173:22, 206:13, 216:7, 246:19, 252:1, 273:21 tool [1] - 178:6 tools [1] - 276:8 top [15] - 9:3, 16:20, 38:22, 45:6, 45:7, 47:23, 96:20, 118:15, 134:14, 139:13, 140:23, 140:25, 186:21, 195:6 topic [7] - 124:18, 127:21, 265:21, 268:14, 270:16, 270:17, 272:4 topics [2] - 31:5, 123:25 total [14] - 50:1, 54:23,	67:19, 69:11, 71:21, 96:22, 96:23, 96:25, 97:2, 97:5, 103:9, 103:23, 155:10 totality [5] - 21:6, 130:5, 134:16, 153:17, 207:23 totalled [1] - 71:21 totally [1] - 235:8 totals [1] - 56:13 totem [1] - 263:19 totem-pole [1] - 263:19 touched [2] - 179:19, 183:11 tough [1] - 12:12 toward [1] - 140:23 Tower [2] - 3:4, 4:18 track [2] - 176:2, 176:7 tracked [1] - 244:14 tracks [1] - 244:2 trade [2] - 37:16, 41:8 Traffic [1] - 13:1 trailing [13] - 85:3, 85:7, 85:12, 87:18, 91:5, 92:3, 92:7, 92:17, 93:7, 93:8, 98:13, 276:6 trained [2] - 142:13, 159:18 training [2] - 15:15, 158:22 transaction [11] - 23:12, 42:12, 48:21, 65:7, 71:13, 71:16, 80:20, 84:14, 92:6, 93:1, 271:10 transactional [10] - 26:19, 27:14, 44:9, 44:10, 45:11, 45:14, 57:12, 57:15, 61:21, 95:23 transactions [29] - 16:13, 46:4, 46:19, 47:19, 47:25, 48:25, 49:5, 49:8, 49:19, 49:23, 58:23, 69:4, 73:6, 86:10, 89:16, 92:9, 93:9, 103:4, 103:6, 103:22, 104:15, 105:18, 143:2, 271:1, 271:4, 271:13, 272:1, 272:20, 273:1 transcript [9] - 6:19, 49:15, 188:22, 211:24, 221:6, 228:21, 229:13, 235:11, 278:20 transfer [1] - 136:8	transition [3] - 12:12, 29:17, 59:17 transmitted [1] - 75:9 treat [1] - 142:12 Treatment [1] - 118:22 treatment [1] - 142:1 treats [1] - 225:23 tree [1] - 86:11 tremendously [1] - 222:22 trend [2] - 55:3, 60:1 trends [4] - 55:1, 175:20, 200:11 Trial [1] - 278:15 TRIAL [1] - 1:16 trial [12] - 19:6, 22:12, 30:17, 30:22, 39:16, 39:23, 43:16, 51:12, 54:17, 254:1, 254:2, 257:12 tried [8] - 206:2, 223:6, 223:14, 229:2, 230:24, 247:6, 247:13, 250:18 trigger [21] - 68:1, 75:16, 75:17, 77:18, 77:19, 80:12, 80:14, 80:21, 82:16, 82:19, 82:20, 84:13, 88:11, 88:16, 88:21, 89:14, 97:24, 214:24, 228:11, 233:7, 247:4 triggered [8] - 77:12, 85:8, 215:13, 215:16, 215:17, 226:24, 233:14 triggering [2] - 79:11, 81:23 triggers [4] - 75:20, 81:3, 81:6, 215:12 trouble [1] - 162:8 truck [1] - 193:16 true [32] - 51:18, 51:23, 63:7, 104:20, 129:13, 134:3, 134:4, 135:13, 143:16, 145:18, 149:23, 156:24, 159:24, 162:2, 167:11, 168:16, 181:23, 183:25, 184:19, 184:20, 206:25, 210:14, 218:19, 220:16, 232:24, 234:22, 234:23, 242:4, 254:7, 254:20, 257:19 True [19] - 116:5,
---	---	--	---	--

<p>116:23, 117:9, 117:15, 127:25, 128:14, 129:12, 133:19, 134:9, 138:1, 143:20, 155:17, 155:20, 156:17, 159:23, 168:24, 169:1, 184:15, 185:17</p> <p>trust [2] - 181:4, 240:3</p> <p>truth [9] - 142:2, 164:11, 164:23, 169:6, 170:15, 171:13, 172:5, 173:3, 220:14</p> <p>truthful [4] - 148:9, 189:8, 229:5, 235:14</p> <p>truthfully [6] - 157:9, 165:4, 165:16, 165:25, 166:8, 261:24</p> <p>try [22] - 27:18, 27:19, 28:23, 82:11, 83:3, 115:17, 128:5, 145:25, 160:22, 178:7, 221:20, 224:9, 225:8, 239:21, 240:7, 244:5, 246:3, 248:18, 249:11, 272:16</p> <p>trying [24] - 45:4, 68:18, 70:8, 78:21, 82:24, 84:15, 84:17, 90:11, 110:18, 117:24, 118:2, 121:22, 122:6, 123:2, 128:3, 189:25, 197:21, 202:1, 232:15, 234:4, 239:10, 243:9, 249:1, 249:18</p> <p>turn [6] - 16:25, 66:15, 163:6, 163:15, 197:17, 237:18</p> <p>turned [3] - 89:5, 89:8, 97:14</p> <p>turns [1] - 87:7</p> <p>Twelfth [3] - 4:13, 4:15, 5:5</p> <p>twice [5] - 85:12, 91:5, 92:3, 98:13, 189:3</p> <p>two [49] - 8:9, 8:11, 9:3, 9:12, 9:16, 9:23, 9:24, 13:11, 17:9, 19:21, 43:2, 46:7, 52:10, 53:3, 57:11, 58:15, 61:3, 63:4, 73:25, 92:10, 92:13, 93:3, 93:16, 98:14,</p>	<p>126:17, 150:20, 161:1, 162:3, 184:23, 209:1, 209:16, 209:17, 211:7, 219:6, 219:10, 219:23, 220:1, 225:13, 226:19, 228:16, 237:11, 237:23, 248:20, 268:16, 268:20, 272:25, 274:11, 274:19, 274:24</p> <p>two-step [2] - 63:4, 73:25</p> <p>Type [4] - 168:8, 168:18, 169:3, 169:12</p> <p>type [19] - 53:1, 56:9, 59:13, 60:13, 62:4, 70:25, 73:15, 77:18, 79:12, 84:7, 92:4, 115:5, 119:22, 126:25, 128:22, 128:25, 196:4, 250:10</p> <p>types [13] - 17:15, 17:19, 29:22, 35:23, 41:22, 42:7, 70:25, 83:25, 87:1, 193:11, 196:25, 250:19, 270:9</p> <p>typically [1] - 82:24</p>	<p>192:17, 215:10, 215:14, 227:15, 228:13, 228:23, 231:9, 231:24, 232:21, 241:9, 244:16, 245:6, 256:19, 257:22, 269:22</p> <p>undergo [3] - 168:20, 169:4, 169:14</p> <p>Understood [1] - 161:2</p> <p>understood [4] - 28:2, 33:10, 244:7</p> <p>undertake [1] - 135:6</p> <p>undisclosed [1] - 111:5</p> <p>undisputed [1] - 85:25</p> <p>unexpected [1] - 12:18</p> <p>unfair [1] - 147:8</p> <p>uniform [5] - 11:13, 12:10, 12:11, 12:12, 12:16</p> <p>unintended [1] - 183:19</p> <p>uninterrupted [1] - 148:18</p> <p>unique [2] - 11:9, 11:14</p> <p>uniquely [2] - 200:2, 201:1</p> <p>Unit [3] - 11:16, 11:24, 175:4</p> <p>unit [4] - 11:18, 11:19, 12:13, 55:25</p> <p>United [10] - 7:2, 21:24, 121:21, 122:10, 150:11, 156:2, 165:19, 180:15, 253:19, 254:24</p> <p>UNITED [2] - 1:1, 1:17</p> <p>units [47] - 46:24, 47:4, 47:19, 47:20, 49:2, 49:20, 49:21, 50:1, 55:23, 57:6, 57:18, 58:21, 93:23, 95:3, 95:7, 96:21, 96:23, 96:24, 96:25, 97:2, 97:3, 97:5, 98:1, 98:4, 98:9, 98:10, 98:17, 100:5, 100:7, 100:12, 100:13, 100:16, 100:19, 100:23, 101:1, 101:5, 101:8, 101:10, 101:12, 101:13, 101:14, 101:17, 101:18,</p>	<p>101:19, 101:20</p> <p>University [1] - 21:16</p> <p>unless [6] - 27:8, 46:16, 94:10, 117:11, 119:15, 144:5</p> <p>unsound [1] - 99:5</p> <p>unusual [11] - 82:24, 83:1, 203:5, 203:7, 204:8, 204:13, 204:18, 204:19, 205:9, 248:10</p> <p>up [109] - 8:5, 11:12, 12:23, 13:19, 15:24, 25:23, 26:9, 29:23, 36:6, 37:11, 40:4, 41:2, 44:7, 51:12, 55:3, 56:18, 56:21, 60:5, 64:4, 66:12, 66:20, 74:10, 74:12, 79:5, 81:1, 86:11, 90:2, 90:8, 92:14, 93:20, 96:8, 102:25, 104:25, 107:15, 113:14, 114:2, 120:5, 120:11, 126:9, 131:8, 134:1, 138:24, 146:13, 146:20, 152:6, 152:15, 157:11, 161:10, 161:20, 162:23, 163:8, 164:15, 164:16, 169:19, 172:11, 174:23, 182:3, 186:18, 186:20, 188:22, 192:16, 198:3, 199:8, 200:18, 202:13, 202:21, 204:22, 209:6, 211:23, 212:14, 212:21, 213:16, 215:4, 219:2, 222:15, 222:25, 224:22, 225:3, 228:21, 230:22, 235:10, 237:2, 238:25, 239:14, 239:18, 239:22, 240:3, 240:14, 242:15, 242:16, 244:9, 245:14, 245:20, 247:16, 249:1, 249:14, 249:18, 250:21, 252:8, 253:18, 256:15, 259:23, 261:17, 264:8, 267:3, 267:10, 270:22,</p>	<p>270:23</p> <p>upper [3] - 17:24, 119:2, 195:16</p> <p>upward [1] - 55:3</p> <p>usable [1] - 210:24</p> <p>useful [2] - 191:10, 192:17</p> <p>Usefulness [1] - 192:10</p> <p>uses [2] - 201:11, 226:16</p> <p>usual [2] - 83:4, 84:19</p> <p>utilize [1] - 185:1</p>
V				
<p>VA [7] - 271:16, 272:3, 272:9, 273:6, 273:16, 273:21, 273:22</p> <p>vague [2] - 62:12, 62:14</p> <p>valid [3] - 32:17, 171:19, 236:19</p> <p>validated [1] - 237:1</p> <p>validity [1] - 52:14</p> <p>valuable [1] - 223:16</p> <p>various [5] - 82:2, 136:12, 138:9, 208:19, 265:25</p> <p>vast [1] - 117:23</p> <p>vault [1] - 94:25</p> <p>vein [1] - 131:6</p> <p>Ventura [1] - 3:18</p> <p>verbal [1] - 27:24</p> <p>verification [1] - 171:24</p> <p>version [5] - 51:18, 51:22, 51:23, 94:22, 94:23</p> <p>versus [2] - 127:25, 260:8</p> <p>vertical [1] - 57:5</p> <p>vet [1] - 168:2</p> <p>veterinarian [1] - 84:3</p> <p>veterinarian's [1] - 84:3</p> <p>veterinarians [2] - 17:7, 84:7</p> <p>vetting [1] - 169:23</p> <p>video [3] - 164:18, 164:22, 235:11</p> <p>Video [1] - 165:2</p> <p>view [8] - 73:22, 78:21, 123:9, 123:14, 186:15, 217:6, 272:8, 272:16</p> <p>violated [1] - 32:5</p> <p>violation [2] - 120:16, 171:2</p>				

<p>VIRGINIA [2] - 1:1, 1:18</p> <p>Virginia [50] - 4:18, 7:3, 7:4, 15:13, 44:13, 46:21, 46:25, 47:5, 50:3, 54:25, 56:5, 59:4, 59:9, 67:7, 70:21, 93:1, 97:17, 103:5, 106:5, 106:10, 106:15, 107:1, 107:6, 107:24, 108:6, 108:18, 109:4, 110:9, 111:2, 111:22, 112:6, 112:25, 118:14, 119:11, 124:23, 125:11, 125:17, 126:6, 126:15, 126:20, 131:15, 131:16, 151:4, 162:24, 173:17, 190:16, 191:17, 192:4, 207:16, 271:2</p> <p>visibility [1] - 178:10</p> <p>visit [1] - 169:11</p> <p>visits [1] - 276:20</p> <p>visual [1] - 56:12</p> <p>volume [10] - 46:4, 48:11, 50:1, 54:23, 59:3, 83:3, 97:16, 173:8, 173:11, 179:10</p> <p>VOLUME [1] - 1:16</p> <p>volumes [2] - 24:19, 59:12</p> <p>voluminous [1] - 24:2</p> <p>vs [2] - 40:23, 278:22</p>	<p>warranted [1] - 76:12</p> <p>warrants [1] - 16:7</p> <p>Washington [9] - 2:11, 4:7, 4:14, 4:16, 5:5, 5:12, 29:13, 167:9, 167:10</p> <p>watch [1] - 158:19</p> <p>watched [5] - 233:15, 256:4, 259:3, 259:15, 259:20</p> <p>watching [1] - 263:12</p> <p>Wayne [2] - 11:1, 11:5</p> <p>ways [3] - 48:18, 138:9, 175:16</p> <p>wearing [1] - 12:11</p> <p>WEBB [1] - 3:11</p> <p>Webb [1] - 3:12</p> <p>website [4] - 173:23, 173:25, 174:5, 202:15</p> <p>week [6] - 137:13, 160:2, 160:3, 239:22</p> <p>weekly [1] - 95:10</p> <p>weeks [5] - 15:12, 15:14, 209:17, 240:1, 240:11</p> <p>weight [2] - 9:20, 63:10</p> <p>welcome [1] - 152:4</p> <p>WEST [2] - 1:1, 1:18</p> <p>West [48] - 7:3, 7:4, 44:12, 46:20, 46:25, 47:5, 50:3, 54:25, 56:4, 59:4, 59:9, 67:7, 70:20, 93:1, 97:17, 103:5, 106:5, 106:10, 106:14, 106:25, 107:6, 107:24, 108:6, 108:18, 109:4, 110:9, 111:2, 111:22, 112:6, 112:25, 118:14, 119:11, 124:22, 125:11, 125:17, 126:5, 126:15, 126:20, 131:14, 131:15, 151:4, 162:23, 173:17, 190:16, 191:17, 192:3, 207:16, 271:2</p> <p>whacking [1] - 182:12</p> <p>Wheeling [4] - 64:17, 64:24, 64:25, 69:10</p> <p>white [1] - 241:5</p> <p>whole [6] - 21:8, 21:11, 117:5, 129:20, 129:23, 160:3</p> <p>wholesale [4] - 19:23,</p>	<p>22:3, 40:25, 143:4</p> <p>wholesalers [1] - 258:16</p> <p>wholesalers' [1] - 257:4</p> <p>WICHT [2] - 4:12, 7:22</p> <p>wide [2] - 30:20, 142:12</p> <p>widespread [1] - 109:18</p> <p>willful [2] - 265:3, 265:7</p> <p>Williams [2] - 4:13, 5:4</p> <p>willing [1] - 174:6</p> <p>window [6] - 33:13, 244:9, 251:11, 253:10, 275:10, 275:15</p> <p>winnow [1] - 52:17</p> <p>withdraw [1] - 215:25</p> <p>witness [28] - 10:2, 10:4, 13:7, 13:20, 13:24, 31:11, 31:16, 35:5, 36:21, 42:4, 52:16, 59:1, 65:11, 65:12, 65:19, 65:20, 90:7, 113:22, 119:18, 119:19, 119:20, 139:6, 147:8, 165:9, 187:13, 189:20, 217:21, 234:4</p> <p>WITNESS [51] - 10:7, 10:9, 10:12, 21:17, 36:23, 40:6, 40:15, 43:10, 48:4, 48:6, 60:23, 62:10, 63:16, 64:3, 69:16, 69:20, 75:5, 75:8, 77:25, 78:17, 80:5, 80:9, 91:14, 94:3, 99:20, 100:10, 105:11, 106:21, 108:9, 108:21, 109:15, 110:19, 111:15, 128:9, 139:9, 145:11, 152:9, 155:2, 160:24, 178:3, 190:19, 197:9, 207:14, 207:20, 221:16, 239:9, 263:16, 267:8, 277:12, 278:12, 278:14</p> <p>witness's [3] - 146:24, 221:9, 234:1</p> <p>witnesses [3] - 42:18, 43:20, 86:6</p> <p>witnesses' [1] -</p>	<p>233:18</p> <p>WOELFEL [1] - 3:9</p> <p>Woelfel [2] - 3:9</p> <p>word [4] - 46:13, 89:5, 93:7, 204:1</p> <p>words [5] - 75:20, 76:4, 139:23, 253:13, 255:8</p> <p>works [6] - 87:16, 230:7, 232:15, 234:3, 241:8, 246:21</p> <p>world [9] - 197:1, 220:11, 220:16, 220:23, 222:2, 223:3, 224:11, 235:3, 244:3</p> <p>worse [3] - 145:19, 146:4, 146:6</p> <p>worth [3] - 9:21, 192:15, 240:12</p> <p>wound [1] - 66:12</p> <p>Wright [8] - 174:14, 175:4, 258:22, 259:7, 259:10, 259:14, 260:19</p> <p>Wright's [1] - 260:12</p> <p>write [6] - 116:16, 116:20, 156:8, 218:21, 230:3, 242:8</p> <p>writes [1] - 269:9</p> <p>writing [4] - 18:25, 131:9, 247:11</p> <p>written [10] - 27:25, 118:17, 129:10, 130:19, 132:15, 134:8, 162:4, 198:20, 222:5, 241:13</p> <p>wrote [5] - 127:18, 165:21, 190:1, 215:1, 216:13</p> <p>WU [1] - 5:10</p> <p>WV [7] - 2:8, 3:10, 3:13, 4:19, 5:15, 6:9, 202:14</p>	<p>years [26] - 11:3, 11:23, 12:6, 12:13, 12:24, 18:5, 38:5, 103:10, 146:8, 146:9, 159:3, 161:18, 161:20, 161:21, 166:16, 166:23, 184:23, 248:20, 250:1, 250:6, 258:13</p> <p>yes/no [2] - 128:5, 128:6</p> <p>yesterday [4] - 8:5, 8:8, 9:5, 65:13</p> <p>York [7] - 3:5, 157:6, 164:15, 173:19, 211:5, 211:18, 262:9</p> <p>yourself [2] - 10:21, 252:14</p> <p>Yugoslavian [1] - 18:17</p>
Z				
<p>Zimmerman [2] - 54:5, 263:10</p> <p>Zoom [1] - 235:15</p>				
X				
<p>Xanax [2] - 19:1, 19:21</p>				
Y				
<p>year [18] - 21:20, 22:14, 74:16, 103:8, 176:3, 180:12, 191:25, 192:1, 203:13, 231:3, 232:6, 234:20, 244:8, 252:13, 253:9</p>				